Legitimising Supranational Risk Regulation: The EU Pharmaceutical and Food Safety Regimes

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Abstract

From the point of democratic legitimacy, supranational risk regulation is problematic in two respects: Firstly, as part of EU competencies, it may suffer from the EU's 'democratic deficit' like all other kinds of supranational policy-making. And secondly, supranational risk regulation often takes place in rather technocratic, intransparent and closed bodies like committees or agencies which hide it from public scrutiny. This article examines whether and how supranational risk regulation can nevertheless be legitimised. Therefore, it examines different mechanisms which may legitimise policy-making. On the one hand, input legitimacy derives from procedures, which allow stakeholders to articulate their interests in supranational risk regulation. And on the other hand, output legitimacy results from the quality of the final policy outcomes of supranational regulatory regimes. A crucial question is the relationship between output- and input legitimacy: Does strong input from stakeholders automatically result in adequate regulatory policies, or does it disturb the efficiency and thus output legitimacy of regulatory regimes? To answer this question, the two cases of pharmaceutical and foodstuff regulation in the EU are compared. The result of this empirical analysis is that pharmaceutical authorisation derives its legitimacy mainly from output factors, whereas foodstuff regulation aims to

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increase its legitimacy by purposeful inclusion of stakeholders. Given the crisis of consumer confidence in EU food safety legislation, the article concludes that supranational regulatory regimes are more dependent on output than on input legitimacy.

1 Introduction: Input and Output vs. Input or Output

Supranational risk regulation – i.e. the regulation of potentially dangerous products in the European Single Market – is problematic in respect to its democratic legitimacy for two reasons. Firstly, like all supranational policy-making, it could suffer from the EU's 'democratic deficit'. It is often argued that the EU lacks democratic legitimacy, because it is not well-enough controlled by a strong parliament (e.g. Follesdal/Hix 2006), it has a neo-liberal bias (Scharpf 1999) and it is too distant from its citizens, who do not constitute a European demos (Weiler 1995). If these arguments hold true, this would of course also affect the regulation of the Single Market by the Commission and various expert bodies. And secondly, supranational risk regulation is often even more detached from public scrutiny than other areas of EU policy-making. It usually takes place in technocratic bodies like expert and member state committees or regulatory agencies. These bodies are not democratically elected and are thus not directly responsible to EU citizens. Besides, their decision-making is often very intransparent or even takes place behind closed doors. Consequently, much criticism which is addressed to the EU in total might hold even truer for one of its core competencies – the regulation of the Single Market.

As a result of these problems, it is important to ask which institutional mechanisms may strengthen the legitimacy of supranational risk regulation. Therefore, the following article is built on the distinction between input and output legitimacy as it has been repeatedly

suggested by Scharpf (e.g. 1999; 2004). Accordingly, input legitimacy derives from 'government by the people', i.e. whenever citizens are able to articulate their will within policy-making. They may do so in national parliamentary elections, in the elections for the European Parliament (EP) or during stakeholder consultations. In contrast, output legitimacy results from 'government for the people', i.e. whenever policies meet the interests of concerned stakeholders. In order to ensure this kind of legitimacy, regulatory regimes should be accountable to various stakeholders for their decisions.

As soon as supranational risk regulation is delegated to the Commission, various expert bodies or member state committees, policy-making becomes differentiated between legislation and single regulatory policies (Gehring 2005). In order to evaluate the legitimacy of supranational risk regulation, both levels of decision-making have to be analysed. It is not only important to consider how regulatory regimes operate, but also how the basic rules of decision-making were adopted. Thereby, the legitimising factors need not be the same on both levels. On the legislative level, the founding acts of regulatory regimes are adopted within the usual legislative procedures of the EU. Thus, they should be legitimised by the usual input factors like participation of member states' governments in the Council, involvement of the European Parliament (EP) and consultation of stakeholders. However, on the level of regulatory policies, input legitimacy becomes less important, the more political bodies are restricted by the rules adopted at the legislative level. Thus the importance of output legitimacy is necessarily increasing.

In the following, this article explores the crucial relationship between input and output legitimacy of supranational risk regulation using the example of the EU regulatory regimes for pharmaceuticals and foodstuffs. It starts with operationalising variables which stand for high input and output legitimacy.

Thereafter, the relationship between the two legitimising factors at both levels of supranational risk regulation is presented in more detail. The empirical part of the article analyses input and output legitimacy of the two supranational regimes for pharmaceuticals and foodstuffs. Whereas EU pharmaceutical authorisation derives its legitimacy mainly from output factors, EU foodstuff regulation aims to strengthen input factors in order to regain legitimacy after the BSE scandal. Recent experiences suggest that this strategy in the foodstuff sector is not suitable for the restoration of consumer confidence. Thus, the article concludes that output legitimacy is more important for the day-to-day operation of supranational regulatory regimes than input legitimacy – a result which is more in line with Majone's (1996; 1998; 2001) concept of independent regulatory agencies than with Joerges' and Neyer's (1997; 2006) deliberative supranationalism.

2 Legitimising Factors of Supranational Risk Regulation

The potential legitimacy deficit of the EU has bothered the academic discussion to an immense degree over the last two decades (e.g. Höreth 1999; Rittberger 2004). Thereby, scholars widely disagree about the most important sources of legitimacy, about the existence or non-existence of a legitimacy deficit and about possible solutions. One range of scholars sees member states as the main source of legitimacy within the EU and concludes that a legitimacy deficit does not exist (e.g. Moravcsik 2002). Another view is that the EU suffers from a democratic deficit, because the EP is too weak and does not elect the executive (e.g. Crombez 2003; Follesdal/Hix 2006). A totally different position is held by Scharpf (1996a; 1999), who argues that the EU mainly suffers from a legitimacy deficit, because it leads to unbalanced policies. And finally, Majone (2000) argues that the EU suffers from a credibility

crisis, because it lacks the necessary capacities to regulate the Single Market.
It is obvious that these four approaches are not compatible with each other, because they agree neither on the sources of, nor on the solutions to a legitimacy deficit. Whereas some share the view that legitimacy should be based on input factors, others agree that the EU's policy output is mainly responsible for its legitimacy. Whereas some assume that the member states are the only source of legitimacy, others assign the EU itself some capacity to provide legitimacy. The question to be explored in the following section is how all these different factors are able to contribute to the legitimacy of supranational risk regulation. Should EU regulatory regimes be legitimised by input from the member states or from the EP? Can supranational regulatory regimes derive legitimacy from their own policy outputs or do they have to rely on individual action of the member states? And finally, how are the different input and output factors related to each other?

2.1 Input Legitimacy: Member States, European Parliament and Stakeholders

The main argument for why the EU should rely on the member states as the most important source of legitimacy is that it lacks a demos which could justify majority rule (Scharpf 1999, 6-42; 2004; Weiler 1995). According to this view, majority rule is only regarded as legitimate if people share a common identity and some degree of solidarity. This allows them to accept the rule of a winning majority if they find themselves within a losing minority. However, the EU is not based on one European people, but on 27 different nations. Between these different peoples, the necessary solidarity for majority rule is deemed to be missing. Accordingly, the only way to legitimise EU policy-making is basing decisions on consensus of all member states. Qualified majority voting in the Council and participation of the

EP increase the legitimacy deficit rather than reduce it. Majority rule in the Council allows that some member states can be overruled, and that citizens of these member states cannot hold their governments responsible for such decisions. And increasing influence of the EP even reinforces this problem, because the threshold for majority vote is even lower.

However, one may question whether majority rule is really that problematic in all circumstances. As long as the EU redistributes wealth between member states, the necessary solidarity between different states is indeed lacking. Such redistributions are zero-sum games, where some parties win what other parties loose, and the need for legitimacy is thus very high (Scharpf 2004). But most policies of the EU – and foremost all product regulations – do not resemble zero-sum games. Instead, harmonisations of product standards are usually coordination problems which have only second order distributive consequences. Here, all actors should have an interest in cooperative solutions in order not to lose efficiency gains of the Single Market. Thus, the need for legitimacy is much lower than for purely re-distributive policies (Majone 1996, 284-301). It is realistic to assume that actors accept relative losses in the short-run if cooperation meets their interests in the long-run. Only long-term cooperation needs to be legitimised by consensus between the member states, whereas single policies may be adopted by majority rule.

If the categorical necessity of unanimous rule is given up, intergovernmentalists lose their strongest argument against legitimisation of policy-making by the EP. As soon as majority rule becomes normatively acceptable, decision-making by the EP is ceteris paribus at least as legitimate as decision-making by the Council. The so-called legitimacy chain, i.e. the connection between citizens and decision-makers, is much shorter for the EP than for the Council. The former is directly elected by European citizens, and the legitimacy chain is thus relatively short. In contrast, the Council is only

indirectly legitimised: citizens vote for their national parliaments, parliaments usually elect heads of governments, and governments send ministers to Council meetings. It is obvious that such a long legitimacy chain makes it extremely difficult to influence decision-making in the Council ex ante with national elections. As a result, one cannot see why the Council should be better able to legitimise supranational risk regulation than the EP. Even if one holds the position that the Council is a necessary second chamber, additional influence of the EP within the legislative process surely increases the input legitimacy of EU policy-making.

Besides participation of the member states and the EP, a third mechanism for increasing input legitimacy of supranational risk regulation is the consultation of stakeholders and civil society. However, it is important that the influence of different interests is well balanced. Usually, concrete economic interests are favoured vis-à-vis other, more diffuse interests like those of health and consumer protection. Concrete interests are per se easier to organise and thus to represent than diffuse interests (Olson 1968, 52-64). And the whole Single Market is of course a project which even further favours producer vis-à-vis consumer interests (e.g. Scharpf 1997a). In order to increase input legitimacy of EU policy-making, these advantages for concrete economic interests should be outbalanced by privileged access of diffuse interests to EU policy-making. Here again, involvement of the EP becomes important. Traditionally, the EP has become the ‘Champion of Diffuse Interests’ (Pollack 1997). Because it is the only directly elected body at the EU level, it is most of all dependent on broad public support, and thus, it tries to hold positions which are favoured by large majorities in public.

2.2 Output Legitimacy: Efficient Policy-Making and Accountability Mechanisms

Another crucial issue for the legitimacy of EU risk regulation is whether supranational regulatory regimes may provide output legitimacy on their own, or whether member states' individual action would be more efficient. Scharpf (1997a) regards the EU's potential for positive integration as rather limited, and is therefore sceptical in respect to its output legitimacy. Whereas negative integration is written down in the treaties, positive integration needs to pass through the needle's eye of the Council, where a high degree of consensus is necessary in order to adopt legislation. Thus, the EU favours deregulation vis-à-vis re-regulation, and its output legitimacy is low.

However, Scharpf (1996b) himself distinguishes between two kinds of regulatory standards which are differently difficult to harmonise at the EU level. On the one hand, there are process standards – including most standards of social security – which increase the costs of production, but which have no influence on product quality. These standards are extremely difficult to harmonise at the EU level, because poorer member states would lose their competitiveness vis-à-vis richer member states if social standards were harmonised. On the other hand, product standards – including most measures of health and consumer protection – are less difficult to harmonise. The member states face coordination problems with distributive consequences when they adopt harmonised product standards. They would all profit from common standards and they only disagree about the form of these standards. Thus, if supranational regulatory regimes help the member states to overcome these coordination problems and to adopt harmonised product standards, they in fact increase the efficiency and output legitimacy of EU policy-making.

Indeed, supranational regulatory regimes may provide more output legitimacy than individual member state action (Menon/Weatherill 2002). If the member states adopt regulatory standards for risky products on their own, they have to choose whether or not these prevail over other member states' standards, or whether the

mutual recognition principle applies. In the former case, the member states face enormous difficulties with establishing the Single Market, because national regulatory standards constitute non-tariff barriers to trade. Thus, the member states may forgo the efficiency gains, which are inherent in the Single Market and increasing international trade. And in the latter case, the member states face the danger of regulatory competition where the lowest standards prevail. Thus, the level of health and consumer protection is likely to decline – at least in member states with formerly high standards. At least for risky products, the member states have difficulties achieving both the Single Market and an adequate level of health and consumer protection on their own. Consequently, supranational regimes may provide output legitimacy if they are able to achieve both policy objectives at the same time.

In order to ensure that supranational regulatory regimes fulfil their tasks of market integration and risk regulation in the long-term interests of the concerned stakeholders, they should be subject to *ex post* scrutiny (e.g. Dehousse 1999; Everson 1995; Majone 1996, 284-301). If the respective regimes cannot be held accountable for their action, they might easily be captured by particularistic interests, or they might develop their own interests in an increasing regulation of their sector – either under- or over-regulation might be the result – and output legitimacy would decline. In order to ensure accountability, three different mechanisms can be distinguished (May 2007):[1] supranational regulatory regimes can be politically accountable to the governments of the member states and the EP, they can be professionally accountable to

[1] Originally, May (2007) lists four accountability mechanisms. However, bureaucratic accountability does not play an important role in the case of supranational risk regulation, because the implementation of EU decisions is left to the member states, which have to ensure the necessary control within their own national administration.

experts and scientist of the member states, and they can be legally accountable to the concerned stakeholders.

Firstly, the member states in the Council usually establish so-called Comitology procedures in order to hold supranational regulatory regimes politically accountable. Whenever expert bodies of regulatory regimes develop scientific opinions, they have to forward them to the Commission, which then develops policy proposals on this basis. These proposals are then subject to the vote of a member state committee and possibly – if the committee denies approval - of the Council. Thus, the regimes' expert bodies are dependent on agreements of the member states in order for their proposals to be adopted. This is of course a very strong accountability mechanism, because it does not only work in the long-run, but also covers day-to-day policy-making. The oversight mechanism reflects the weak position of the EP, which is usually not actively involved within supranational regulatory regimes. It is merely regularly informed about decision-making within the Comitology system (Bradley 1992), but it has no competencies to veto regulatory policies.

Secondly, supranational regulatory regimes should also be professionally accountable to scientists and experts in the regulatory field. This accountability can be achieved by establishing regulatory networks (Dehousse 1997; Krapohl 2007; Majone 1997). EU expert bodies may consist of representatives from member states' regulatory agencies, instead of scientific experts from outside. Thus, supranational regulatory regimes would be embedded within networks of national regulatory agencies. There are two reasons which suggest that such regulatory networks are softer accountability mechanisms than political oversight procedures. On the one hand, representatives of national regulatory authorities act within arm's length of their own governments. Their domestic regulatory agencies themselves are deemed to be, at least partly, independent from political influence. And on the other hand, representatives of national authorities are

scientists and not politicians or bureaucrats. As scientists, it is important for them to build up a reputation of independence and neutrality in order to give their arguments credibility. Networks of regulatory agencies may work as mechanisms which ensure that a reputation can be built, and which sanction the exploitation of such reputations (Majone 1997*).*

And finally, supranational regulatory regimes should be legally accountable to European citizens in general and to the addressees of their regulations in particular. Here, the European courts – namely the ECJ and the Court of First Instance – play an important role, because they may scrutinise regulatory decisions on behalf of EU citizens. The efficiency of this accountability mechanism depends on the precision of substantive decision-making criteria and on the scope of potential plaintiffs. If substantive criteria are imprecise, the discretion of actors within regulatory regimes is wide and it is difficult for courts to scrutinise regulatory policy-making. And many actors should have rights to take legal action against EU decisions in order for European courts to receive enough plaints to hold the respective regimes accountable. Here, it is important that access to European courts is symmetric. Both consumers and producers should have equal opportunities to bring claims before the courts.

In sum, there is a whole range of instruments available to make supranational regulatory regimes accountable to the political bodies, national experts or stakeholders. However, in order to avoid that regimes are captured by the interests of one particular actor or group of society, multiple mechanisms should be applied simultaneously and should work hand in hand. Consequently, the influence of different actors or groups would balance each other. A situation emerges where no one is able to control the regime alone, but where the regime is nevertheless subject of control (Moe 1987).

2.3 The Relationship of Input and Output Legitimacy: How to Legitimise Different Levels of Decision-Making

The remaining question is whether high input legitimacy leads to high output legitimacy, or whether, on the contrary, high input legitimacy disturbs regulatory policy-making and thus reduces output legitimacy. Both hypotheses find support within the academic literature. On the one hand, the concept of deliberative supranationalism from Joerges and Neyer (1997; 2006) implicitly assumes that input and output legitimacy of supranational risk regulation are positively correlated. According to Joerges and Neyer, the EU committee system gains its legitimacy from the fact that it allows a wide inclusion of member states' representatives, experts and stakeholders, who are all deemed to deliberate about the most adequate regulatory policies within the different committees. On the other hand, Majone (1996; 1998; 2001) argues that elected politicians are always under pressure to represent the short-term interests of a particular group of stakeholders. Thus, efficiency and output legitimacy of regulatory policy-making are negatively affected by input legitimacy. To avoid regulatory capture, regulatory policy-making should take place at arm's length from majoritarian politics – which reduces input legitimacy.

The problem of both approaches – the deliberative supranationalism from Joerges and Neyer and the concept of independent regulatory agencies from Majone – is that they only concentrate on the day-to-day operation of regulatory regimes, but neglect their formation. In order to analyse the relationship between input and output legitimacy of supranational risk regulation, it is first of all important to explore the logic behind the establishment of supranational regulatory regimes. The reason why the member states – and eventually the EP – establish such regimes is that they face a dilemma when they decide about regulatory

standards (Krapohl 2009, 21-25; Krapohl/Zurek 2006). Usually, decisions about product standards resemble coordination problems with distributive consequences ('Battle-of-the-Sexes'; Scharpf 1996b). Finding a common standard among the variety of possibilities is indeed no trivial task, because each member state has an interest to vote for the standard with the best distributive consequences for himself (this is usually the standard which is already implemented at home).

The situation gets even more complicated, because some standards are likely to be more efficient than others. Thus, member states do not only have to bargain about the distributive consequences, but they also have to engage in the search for the most efficient solution (Scharpf 1997b, 134). In order to avoid blockades and the fallback on the mutual recognition principle, the member states may delegate agenda-setting or even decision-making competencies to expert bodies. This way, the member states reduce coordination problems, because their agents – which should not be influenced by the same short-term interests as their principals – help them to choose one regulatory solution from the variety of different possible standards. The result is that decision-making becomes differentiated between the legislative level and the level of regulatory decision-making where the broader rules are implemented (Gehring 2005).

A consequence of the functional logic behind the establishment of supranational regulatory regimes is that such regimes are likely to be the more efficient the more the member states are willing to commit themselves to the common rules of the regime. They can do this either by delegating far-reaching competencies to independent agents (the classic argument from Majone; 1996) or by binding all actors within the regime, including themselves, to substantive decision-making criteria – in other words, by legalising the policy area (Abbott et al. 2000). If the member states neither delegated competencies nor legalised the policy area, decision-making would not really be

differentiated and the member states themselves would have to bargain about regulatory standards within member state committees or the Council at the level of regulatory policy-making. Thus, the coordination dilemma would not be solved, but it would only be mirrored within the supranational regulatory regimes.

If the member states decide to establish such regimes and to commit themselves to common regulatory objectives, this has implications for the legitimacy of supranational risk regulation. The more the member states bind themselves and other actors – including the EP – by delegation and legalisation, the more input legitimacy is reduced at the level of regulatory policy-making. If commitment is achieved by delegation to independent expert bodies, democratically elected bodies like member states' governments or the EP no longer participate in decision-making, and thus, they cannot legitimise it with their input. And if commitment is achieved by legalisation of the policy area, elected bodies may participate in decision-making, but they have only limited discretion. Consequently, they cannot react to demands of their constituencies or of interest groups, and input legitimacy declines. As a result, input and output legitimacy are negatively correlated at the level of regulatory decisions – a conclusion which corresponds closely with Majone's concept of independent regulatory agencies (1998; 2000). The more the member states commit themselves within supranational regulatory regimes, the more efficient is the regimes' policy-making and the more they may be legitimised by their output, but input legitimacy declines. On the contrary, if the member states or the EP provide input legitimacy at the level of decision-making, blockades of decision-making are more likely, and therefore efficiency and output legitimacy decline.

In the end, the requirements for legitimate risk regulation differ between the two levels of decision-making. The importance of input legitimacy is restricted to the legislative level where the general procedural and substantive rules for supranational risk regulation are

adopted. These general rules include *inter alia* basic decisions about the level of health and consumer protection, and thus they need to be legitimised by the input of democratically elected bodies and finally by the EU citizens who stand at the end of the delegation chain. However, at the level of regulatory policies, the importance of input legitimacy is restricted. Elected politicians or stakeholders themselves are always in danger of representing particularistic short-term interests in specific regulatory standards. Efficient representation of such interests needs to be avoided, because it may lead to blockades of decision-making or to the adoption of inefficient regulatory standards. As a result, supranational regulatory regimes mainly have to rely on their policy output in order to legitimise their day-to-day operation. In order to ensure this output legitimacy, supranational regulatory regimes should be *ex post* accountable for their decisions to various stakeholders. Thereby, it is of crucial importance that different accountability mechanisms balance each other in order that no particular group of actors is able to capture the regulatory regime and to reduce its output legitimacy.

3 The Legitimacy of EU Pharmaceutical and Foodstuff Regulation

The empirical analysis scrutinises input and output legitimacy of the two supranational regulatory regimes for pharmaceutical and foodstuff regulation in the European Single Market. These two cases have been chosen, because the regulated products have much in common: Both pharmaceuticals and foodstuffs are incorporated by consumers, and consequently, they both could pose enormous risks to their health. Both groups of products have to be regulated against similar threats, e.g. BSE (which can be transmitted via consumption of contaminated beef or vaccines produced from bovine sera) or genetic modifications (green and red

biotechnology). And finally, both supranational regulatory regimes appear rather similar on first view, because they are built up around supranational regulatory agencies which are the European Medicines Agency (EMEA) and the European Food Safety Agency (EFSA).

Of course, structural differences also exist between pharmaceutical and foodstuff regulation. As a result of high investment costs, the market for pharmaceuticals is relatively homogeneous, and only few suppliers compete with each other. Consequently, pharmaceuticals can be subject to pre-marketing control, and need to be authorised before they get access to the Single Market. In contrast, the foodstuff market is much more heterogeneous, and as a result, most foodstuffs are only subject to post-marketing control in Europe. Thus, regulatory authorities only react if problems with foodstuffs are detected, but they do not control every kind of food before it gets access to the Single Market. However, there is one notable exception to this general rule in the foodstuff sector: Genetically modified organisms (GMOs) and genetically modified food (GM food) are also produced by only a few suppliers in Europe, and the respective market is therefore relatively homogeneous. GMOs and GM food are also subject to pre-marketing control, and, in this respect, more closely resemble pharmaceuticals than traditional foodstuffs. This characteristic turns the respective regulatory regime to a crucial case for the following analysis, because it allows one to draw the conclusion that differences in the legitimacy of the regulatory regimes for pharmaceuticals and foodstuffs cannot fully be explained by the differences between pre- and post-marketing control.

3.1 The Case of Pharmaceuticals

Input Factors

On the legislative level, two imbalances can be observed throughout the whole development of EU pharmaceutical authorisation. Firstly, the whole regime was established by the Commission and the Council with only limited influence of the EP. At the beginning of the 1990s, the supranational regulatory regime for pharmaceuticals – including the EMEA – was established within a consultation procedure. Within that procedure, the Commission and the Council were not bound by opinions of the EP (Tsebelis/Garrett 2000; 2001). As a result, nearly no EP amendments were included in the final legislation. Thus, intergovernmental decision-making, with its long delegation chain from member states' citizens via national parliaments to member states' governments within the Council, was the main source of input legitimacy during the establishment of the regime. The situation changed slightly during the latest reform at the beginning of the new millennium, because the reform package was adopted within a consultation procedure (Broscheid/Feick 2005) wherein both the EP and the Council stand on equal footing and are equal legislators (Tsebelis/Garrett 2000; 2001). As a result, the EP was more successful in influencing the final legislation of the reform package. The Council had to accept an extension of the scope of the centralised authorisation procedure, the management board of the agency was supplemented with representatives of stakeholders, and political control by the member states during the Comitology procedure was slightly reduced.

And secondly, the establishment of a single market for medicinal products was clearly a project of the pharmaceutical industry. The concrete interests of pharmaceutical producers can be much more easily organised and articulated than the diffuse interests of patients (Abraham/Lewis 2000, 44-49). This imbalance of strength distinguished the development of the EU regulatory regime for pharmaceuticals. In 1988, the Association of the British Pharmaceutical Industry

initiated the set up of the new authorisation regime in the EU when it published its 'Blueprint for Europe' (Abraham/Lewis 2000, 80-83). Therein, it proposed to establish a European pharmaceutical agency, a centralised authorisation procedure for biotechnologically produced pharmaceuticals, and a decentralised procedure for less innovative products. Of course, this suggestion preached to the choir at the Commission, which saw the chance to Europeanise pharmaceutical authorisation and to expand its own competencies. Within the following legislative process, the basic features of the Commission proposal remained unchanged (Krapohl 2005), and thus the industry's 'Blueprint for Europe' became European law only five years after its publication.

To some extent, the picture of asymmetric influence was repeated during the latest reforms of the regulatory regime at the beginning of the new millennium. These reforms were based on an evaluation report about the EU regulatory regime, which was prepared on behalf of the Commission (Cameron McKenna/Andersen Consulting 2000). To get such an assessment, an extensive survey was conducted among all stakeholders in the field. As a result of the wide spectrum of addressees, the report was supposed to be balanced between different social interests. However, an overwhelming portion of the report deals only with issues which are important for the pharmaceutical industry. Thus, even though the authorisation system was positively evaluated by consumers, the input of the two different groups of stakeholders remained rather asymmetric.

The imbalances between the member states and the pharmaceutical industry on the one hand and the EP and consumers at the other are reflected within the day-to-day operation of the regulatory regime. Firstly, the member states are always directly involved in the authorisation process. Within the centralised procedure, the member states are able to influence decision-making with their interests via a Comitology committee and the

Council. And within the mutual recognition procedure, the member states themselves issue national authorisation decisions. On the contrary, the EP is not engaged in the authorisation process. It is neither involved in any mutual recognition of member states' national authorisations, nor does it participate within the centralised procedure. The EP is only represented within the agency's management board, but this does not intervene in the authorisation process. Consequently, although member states are involved in the authorisation process, the regime's day-to-day decision-making is based on very little input-legitimacy. The delegation-chain from EU citizens via national parliaments and governments to the Council and the member state committee is long, and the EP is not involved at all.

And secondly, as applicants for marketing authorisations, pharmaceutical companies have privileged access to the regime (Abraham/Lewis 2000, 162-167). They may be advised by the pharmaceutical agency before they submit applications, they provide the information on which the agency decides, and both the centralised and decentralised authorisation procedures allow for consultations or hearings of applicants at various stages of the evaluation process. Thus, the applying companies and the agency are engaged in a steady dialogue (Abraham/Lewis 2000, 101-104). This is of course necessary, because applicants are individually dependent on authorisation decisions, and consequently, they need the chance to defend their positions (Collatz 1996, 107-133). However, at the same time, consumer interests do not have any access to the supranational regulatory regime. Decision-making within the regime takes place behind closed doors in order to protect intellectual property of the applying companies, and consumer groups are not consulted.

As a result of these imbalances, the overall input legitimacy of the EU regulatory regime for pharmaceuticals can be regarded as relatively weak.

Both the establishment of the regime and its day-to-day policy-making are dominated by input from the member states and the pharmaceutical industry. Thereby, the legitimising potential of the EP and of consumer groups is missing. The open question is what are the consequences of the low input legitimacy for the regimes efficiency and output legitimacy.

Output Factors

It is often argued that pharmaceutical authorisation suffers from a bias in favour of the pharmaceutical industry – i.e. that it serves more the interests of producers than those of consumers (e.g. Abraham/Lewis 2000; Feick 2005; Permanand/Mossialos 2005). According to critiques, the establishment of a single market by the centralised and the mutual recognition procedure leads to a regulatory competition between the various regulatory authorities at both national and supranational level (e.g. Abraham/Lewis 2000, 147-168). In order to attract applications (and application fees), regulatory authorities might be tempted to lower their evaluation standards, and the pressure for fast approvals of pharmaceuticals leads to less in-depth scrutiny of products by regulatory authorities (Abraham/Lewis 2000, 147-168). However, the effects of a regulatory competition and a pressure towards fast approval times are countervailed by several accountability mechanisms (Gehring/Krapohl 2007). These different accountability mechanisms constitute a system of checks-and-balances which controls the regime, but which does not intervene into its day-to-day decision-making. To put it in other words, whereas no single person or body controls the regime, the regime is nevertheless under control (Moe 1987). As a result, the efficiency and output legitimacy of the supranational regulatory regime is quite high.

Firstly, the regime is accountable to member states' experts of the national regulatory agencies for

pharmaceuticals. Within the centralised procedure, this expert accountability is reached via the recruitment of the regime's most important body, namely the agency's expert committee. Members of this committee are usually recruited from member states' regulatory agencies, and need the scientific resources of their national authorities in order to evaluate applications for marketing authorisations. Within the mutual recognition procedure, expert accountability is reached via the acceptance of national authorisations by the regulatory agencies of other member states. Therefore, the concerned member states' authorisation bodies have to trust the scientific evaluations of the reference member states' agencies. To sum up, the national authorisation bodies for pharmaceuticals establish a regulatory network either inside (centralised procedure) or outside (mutual recognition) the EMEA (Majone 1997). Within this network, all experts of the national agencies are in need of scientific reputation. Without that, they would either not be chosen as rapporteurs (centralised procedure), or their national authorisation decisions would not be accepted by concerned member states (mutual recognition). As a result of this reputation mechanism, the experts of the different national authorisation bodies are accountable vis-à-vis each other and control themselves mutually.

Secondly, within the centralised authorisation procedure, the regime is politically accountable to the Council, which may directly control the regime within a Comitology procedure. The member state committee can reject decision proposals in which case matters are referred to the Council. Then, the Council has the final say on the authorisation of medicinal products. During this political phase, the supranational regime is accountable to the member states in the short-run, because they can intervene directly in its day-to-day operation. However, as the empirical analysis of the centralised procedure demonstrates, the member states rarely use this control mechanism (Krapohl 2005, 105-132), so that it operates more like a fire-alarm than a

police-patrol control (McCubbins/Schwartz 1987). In contrast, the regime's accountability to the EP is rather weak, which mirrors parliament's weak position during the establishment and reform of the regime. The EP recruits only two members of the agency's management board and no members of the expert committee, let alone the Comitology committee. Thus, it is not involved in the regime's day-to-day decision-making.

And finally, the supranational regulatory regime is legally accountable to the European people, including producers and consumers of pharmaceuticals. The extensive legalisation of European pharmaceutical authorisation and a relatively wide scope of plaintiffs lead to strong judicial review of the supranational regulatory regime. However, one problem is that access to European courts is asymmetrically distributed among stakeholders. Producers of pharmaceuticals may always challenge (negative) authorisation decisions, because these are directly addressed to individual companies and directly influence their legal positions (Collatz 1996, 143-146). In contrast, consumers are usually not individually and directly concerned by authorisation decisions, and consequently, they may have some difficulties bringing claims against authorisation decisions before of the European courts. Here again, the interests of consumers are disfavoured against those of producers. Nevertheless, one has to keep in mind that the EU organs and the member states are always entitled to bring claims before of the ECJ. Thus, they could step in if they saw their consumers' health endangered by authorisations of specific products (Gehring/Krapohl 2007).

Despite some asymmetries in the accountability mechanisms of the regime, they are in sum relatively strong. The regime is politically controlled by the Commission and the Council within the Comitology procedure, it is embedded within a regulatory network of national experts, and it is subject to strong judicial review by the European courts. It is important to state that not a single one of these three mechanisms is able

to control the regime in total, but that they complement and balance each other. Altogether, the various control mechanisms constitute a system of checks-and-balances. If one of the three accountability mechanisms does not function properly, the other two might step in and bring the regime back on track. In order to capture regulatory policy-making, interest groups would have to capture all three of these mechanisms – a task which would be extremely difficult, even for the strong pharmaceutical industry.

As a result of these accountability mechanisms, the output legitimacy of the EU regulatory regime for pharmaceuticals is relatively high. An evaluation report – which was conducted on behalf of the Commission at the beginning of the millennium – indicates that both producers and consumers seem to be satisfied with central features of the EU regulatory regime for pharmaceuticals (Cameron McKenna/Andersen Consulting 2000). Thereby, the centralised authorisation procedure – the more 'Europeanised' procedure and surely the core of the supranational regulatory regime – was evaluated more positively than the mutual recognition procedure. An overwhelming majority of both pharmaceutical companies and regulatory authorities was in favour of an extension of either the voluntary or the obligatory scope of the centralised procedure (a demand which was partly implemented by the latest reform in 2004). At least in regard to industry's interests, the problem-solving capacity of the regime is generally high. The limited empirical evidence of consumer satisfaction points in the same direction, and the centralised procedure was favoured by both patients and physicians. Such a preference of the centralised procedure would not be rational if regulatory standards were systematically lowered within the supranational regulatory regime. In such a case, patients and physicians would opt for the mutual recognition procedure, wherein they are more protected by their national regulatory authorities. Thus, regulatory

standards of the supranational regime are at least not lower than within the various national procedures.

3.2 The Case of Foodstuffs

Input Factors

In contrast to the pharmaceutical sector, the EU regulatory regime for foodstuffs – including the EFSA – is not an industry project, but it was established with strong participation of the EP as a reaction to consumer concerns after the BSE scandal. After the British government had to announce in 1996 that BSE might endanger the health of consumers, the EP set up a temporary committee of inquiry in order to scrutinise mismanagement in the case of BSE and threatened to adopt a motion of censure against the Commission (European Parliament 1997; Westlake 1997). On its advice, the Commission immediately reorganised the committee system in the foodstuff sector, and thus, the input from the EP can be seen as the starting signal for the reorganisation of the EU regulatory regime for foodstuffs. But the EP also had significant influence on the more fundamental reforms which followed some years later. Within the inquiry report, the EP demanded a legal basis for food safety legislation within the treaties, the set up of a new agency, the establishment of a general food law and the general application of the co-decision procedure for all food safety legislation. And indeed, the member states included some paragraphs in the treaty amendments of Amsterdam, which made health and consumer protection an independent policy-objective of the EU, and which made application of the co-decision procedure compulsory for such measures (Vos 2000). Consequently, for all legislation adopted after 1997 – i.e. the set up of the EFSA, the

establishment of a general food law, and the reform of the GM food regime – the EP and the Council were equal legislators (Tsebelis/Garrett 2000; 2001). Thus, input-legitimacy increased significantly at the legislative level in the foodstuff sector after 1997.

The EP used its new competencies during the legislative process in two respects. Firstly, it ensured that it itself became represented within the daily operation of the new regulatory regime (Kelemen 2002). The most important body of EFSA is the management board, which appoints the executive director as well as the members of the scientific committee and panels. As a result, the recruitment and composition of the management board was a contentious issue for the legislative actors. In the end, the Council and the EP had to find a compromise and agreed to a management board of 15 members, i.e. 14 members, which are appointed by the Council and the EP on a proposal of the Commission plus one additional member representing the Commission itself. Thus, the EP has as greater influence over the recruitment of EFSA's personnel than the Council. And secondly, the EP successfully represented the diffuse interests of consumers within the legislative process (Kelemen 2002; Pollack 1997). Of the 14 members of the management board, which are recruited by the Council and the EP on a proposal of the Commission, at least four should have a background in consumer organisations and other interest groups involved in the food sector. This way, it is ensured that the diffuse and supposedly weak interests of consumers are always represented within the agency.

Stakeholders are consulted at different stages within the day-to-day decision-making of the new regulatory regime for foodstuffs. EFSA itself has established regular stakeholder consultations. An annual general colloquium gives all stakeholders the chance to access EFSA, regular public consultations and technical meetings allow stakeholders to give their opinions on specific topics, and further colloquia deal with specific

issues in a scientific way. Most importantly, EFSA set up a consultative platform in June 2005. This platform consists of 20 to 30 representatives from interest groups which have a legitimate interest in the food sector. Besides, the Commission set up a new Advisory Group on the Food Chain and Animal and Plant Health in 2004, which replaced the old Advisory Committee on Foodstuffs. Like the consultative platform within EFSA, the Advisory Group consists of representatives from interest groups which have a legitimate interest in the field. As a result, the new regulatory regime for foodstuffs can be accessed much more easily by stakeholders than the previous committee system.

To conclude, input legitimacy of EU foodstuff regulation increased significantly on both the legislative and the regulatory level during the 1990s. Before the BSE scandal, the committee system mainly derived its legitimacy from the representation of member states within the standing committees and the Council. In contrast, during the 1990s, both the EP and consumer groups gained much more influence over the regime. The EP became stronger within the co-decision procedure, and used its new powers to ensure its own standing within the new regime, as well as to represent the diffuse interests of consumers. Besides, regular consultations allow stakeholders to give their input into the regimes day-to-day decision-making.

Output Factors

Before the reform of the EU regulatory regime for foodstuffs at the beginning of the new millennium, the policy-output of the old committee system obviously did not meet the interest of stakeholders. During the BSE crisis, European consumers were not informed about the risk of British beef for ten years (between 1986 and 1996), and after the British government had to admit that British beef might be dangerous, it took another four years until the other member states adopted

strong regulatory measures against the disease (from 1996 to 2000; Krapohl 2003; Krapohl/Zurek 2006). In light of 14 years of insufficient protection against the new cattle disease, consumer mistrust in the EU institutions is easily understandable. And during all these problems with the regulation of BSE, the EU began to authorise the first GMOs and GM foods, which were deemed to be widely distributed within the Single Market (Vogel 2001), but which met heavy scepticism of European consumers (Ansell/Maxwell/Sicurelli 2006). In reaction to consumers mistrust in these new foodstuffs, the member states adopted a de facto moratorium against GMOs and GM food. As a result of this moratorium, the issue of GMO and GM food authorisation became further politicised, which has reduced consumers' confidence even further. The crises in the foodstuff sector were also a problem for the producers of foodstuffs. The BSE crisis led to a total collapse of the European beef market. In 1996, when the British government had to admit the risk of BSE to consumers, the collapse mainly affected the UK market. But in 2000, when BSE was detected in most European countries, the whole Single Market was disturbed. The situation is similar, although less dramatic, in the case of GM food. The political disputes about GMOs and GM food lead to a high degree of uncertainty for producers. It is still unsure whether a market for such products will emerge, and whether investments will pay off in the future. Producers would profit from a more efficient regulatory regime for foodstuffs, because such a regime could regain the confidence of consumers, and this confidence is extremely important for a stable demand for certain foodstuffs.

In order to increase the output legitimacy of EU foodstuff regulation, it is important whether or not the new regulatory regime with the involvement of the EFSA can be held accountable by various actors in the long-run. First of all, the regime should be politically accountable to the legislative actors which were responsible for its establishment. Within the new

regulatory regime, the EP - like the other two legislative actors - is able to influence the most important body of EFSA, which is the management board. As a result, it is at least able to hold the agency responsible in the long-run. However, the EP is still weak in comparison to the member states, which are able to control the regime within a Comitology procedure. Therein, Commission proposals – which may, but need not necessarily be based on the EFSA's scientific advice – are submitted to a member state committee. If proposals are not supported by a qualified majority within this committee, they are passed on to the Council, which then has the final say. Thus, the Council can even influence decision-making of the regime in the short-run, which is still impossible for the EP.

Secondly, the regime should also be accountable to experts of the member states. To establish such a link, an Advisory Forum was established within EFSA. This forum consists of representatives from the national regulatory agencies for foodstuffs, and thus, it follows the example of the expert committee in the pharmaceutical sector. The aim of the Advisory Forum is to create a European regulatory network for foodstuffs, which mobilises already-existing expertise within the member states. However, there is a huge difference between the expert committee in the pharmaceutical sector and the Advisory Forum in the foodstuff sector. The former is the most important body of the regulatory regime for pharmaceuticals, and member states' experts are involved in the crucial phase of decision-making. In contrast, the Advisory Forum in the foodstuff sector has no formal decision-making competencies. It only advises the management board and the scientific committee of the agency. Consequently, this accountability mechanism is much weaker than within the pharmaceutical sector. If member states' experts want to hold the foodstuff regime accountable, they cannot rely on the Advisory Forum. Instead, they have to ask their national

governments to use their political power within the standing committee.

Finally, the foodstuff regime should be legally responsible to the European citizens themselves. However, one has to assess that judicial scrutiny of regulatory policy-making is much more difficult than in the pharmaceutical sector. Most regulatory decisions of the foodstuff regime are not addressed to single applicants, so that there are no natural plaintiffs against such decisions. Stakeholders which are affected by broader regulatory policies have more difficulties demonstrating their direct and individual concern if they want to bring claims before the ECJ or the Court of First Instance. The only exception to this is the case of GM foods, where applicants for marketing authorisations are the direct addressees of authorisation decisions. Judicial review is further weakened by the weak legalisation of the policy area. Both the general food law, as well as the substantive rules for GM food authorisation are still rather broad. As a result, there is little ground on which courts could intervene into regulatory policy-making, and there are few chances for stakeholders to judicially challenge regulatory decisions. Consequently, opposition to the regime can only be expressed politically. Stakeholders may lobby against regulatory decisions in their national governments, which may then try to hold the regime politically accountable.

Although one accountability mechanism – namely the political one - is very strong, accountability is in sum very unbalanced. The regime can be easily held responsible by the member states, but all other actors – the EP, national experts within member states' regulatory authorities, the European courts and EU citizens – are relatively weak and cannot effectively scrutinise the regime. As a result, opposition to the regime must always take the political route. If national experts disagree with a scientific opinion of the EFSA, they can only effectively influence regulatory policy-making via their government representatives in the

standing committee. And also stakeholders can only effectively challenge regulatory decisions if they lobby their national governments. The political accountability mechanism is thus the only one left – but it is also the most dangerous for an efficient functioning of the regime. It always bears the risk that regulatory issues become politicised and influenced by particularistic short-term interests.

Because the new EU regulatory regime for foodstuffs took up its work only some years ago and had some problems during the set up phase (because it was significantly understaffed and had to move from Brussels to Parma in 2005), it is probably too early to reliably measure its efficiency and output legitimacy. However, there is one example which demonstrates that the latest reforms are likely to be only a small improvement in comparison to the old committee system: Although the de facto moratorium on GMOs and GM food was lifted in reaction to the reform of the respective regime, regulatory policy-making in this area remains highly politicised and contested. So far, all authorisations issued by the Commission have met the resistance of a simple majority of the member states, and they have only been adopted, because the Council was not able to build up a qualified majority against authorisation. Thus, if only few member states change their position on GMOs and GM food, a de facto moratorium is still possible. Besides, some stakeholders already expressed their objection to the new regime. In November 2004, Friends of the Earth Europe – which is an international environmental and consumer interest group – published a very critical review of the GMO panel within EFSA (Friends of the Earth 2004). It accused the panel of being unfairly influenced by industry interest. According to the review, one third of the panel members are involved in national evaluations of GMOs, the panel chair and four additional members participate in an industry-dominated research project on GMOs, and the panel once co-opted an ad-hoc expert from the

biotechnological industry. As a result, Friends of the Earth accused EFSA of issuing scientific opinions on GM food that are not based on the precautionary principle, and that are much more industry-friendly than those of the member states. The ongoing resistance of both member states and consumer groups indicate that the issue of GMOs and GM food regulation is always in danger of becoming politicised, and that the respective regime faces difficulties in legitimising itself with its policy output.

4 Conclusion

The two cases at hand indicate that input and output legitimacy of supranational risk regulation are negatively correlated. On the one hand, the EU regulatory regime for pharmaceuticals, with the EMEA at its core, derives its legitimacy mainly from output factors, whereas input legitimacy is rather weak at both the legislative and implementation levels. The establishment of this regime was mainly an industry project and the Council was the strongest legislative actor. Thus, legitimising input from consumers and the EP was missing. This is also reflected within the regime's day-to-day operation, where the member states and the pharmaceutical industry have privileged access. The situation improved only slightly during the latest reform at the beginning of the new millennium, when the EP gained more influence within the co-decision procedure. In contrast, output legitimacy of the pharmaceutical regime is rather strong. The regime is controlled by various accountability mechanisms which balance each other and prevent politicisation of regulatory decision-making.
As a result, both producers and consumers of pharmaceuticals seem to be rather satisfied. On the other hand, the EU regulatory regime for foodstuffs is built on input legitimacy on both the legislative and implementation levels, whereas output legitimacy has

been and is likely to remain rather weak. Due to the BSE crisis and the newly applied co-decision procedure, both consumers and the EP were rather strong during the establishment of the regime. However, the regime is still very much politicised and mainly controlled by the member states within a Comitology procedure. Expert and judicial scrutiny are rather weak and stakeholders have to take the political route in order to challenge the regime's decisions. Thus, it is doubtful whether the regime will prove able to restore consumer confidence lost during the BSE crisis and the ongoing disputes about the authorisation of GM food.

The negative correlation between input and output legitimacy at the level of regulatory policy-making is more in line with the concept of independent regulatory agencies from Majone than with the deliberative supranationalism from Joerges and Neyer. According to the latter, input and output legitimacy should be positively correlated, and consequently, output legitimacy should be strong for foodstuff regulation and weak for pharmaceutical authorisation. However, the opposite is the case: As Majone would have predicted, the politicisation of the foodstuff regime seems to disturb regulatory policy-making, and output legitimacy is therefore low. In contrast, the system of checks-and-balances within the pharmaceutical regime prevents such a politicisation and leads to rather strong output legitimacy. The pharmaceutical regime might be an 'undemocratic technocracy', but it fulfils is tasks much better than the politicised foodstuff regime. Thus, the pharmaceutical regime might be undemocratic in regard to its input, but it nevertheless enjoys acceptance by citizens due to its strong output. In contrast, the foodstuff regime might be more democratic, but it is not able to restore consumer confidence in the safety of their food and in the regulatory competencies of the EU regulatory bodies.

The final question is how the situation in the foodstuff sector could be improved. Obviously, the ongoing politicisation of the regime is the wrong way. Instead,

the participation of stakeholders – including the member states, the EP and consumer groups – within the day-to-day operation of the regime should be reduced. The regime should become more independent and more legalised. In order to replace the resulting lack of input legitimacy, more accountability mechanisms should be introduced. Experts from member states' regulatory authorities for foodstuffs should be able to challenge the regime's decisions without taking the loop way of political control. And citizens should be able to hold the regime accountable by challenging its decisions in front of the European courts. Therefore, the scope of potential plaintiffs should be widened and legalisation of the sector should be strengthened in order that the European courts may intervene more easily into regulatory policy-making. In the end, a system of checks-and-balances as in the pharmaceutical sector would emerge, wherein no one body directly controls the regime, but the regime is nevertheless under control (Moe 1987).

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