

Input or Output?

How to Legitimise Supranational Risk Regulation

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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. This might come about through participation of democratically elected governments, the European Parliament or interest groups themselves. And on the other hand, output legitimacy results from the quality of the final policy outcomes of supranational regulatory regimes. In order to ensure that supranational risk regulation meets the interests of stakeholders in the long-run, it needs to be ensured that the respective regimes can be held accountable for their decisions. A crucial question is the relationship between output- and input legitimacy: Does strong input from stakeholders automatically result in adequate 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 increase its legitimacy by purposeful inclusion of stakeholders. Given the crisis of consumer confidence in EU food safety legislation, the article comes to the conclusion that there is a trade-off between input and output legitimacy of supranational risk regulation, and that supranational regulatory regimes are more dependent on output than on input factors.

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 might 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 and Hix 2006), it has a neo-liberal bias (Scharpf 1999) and it is too distant from its citizens, which 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 takes even place behind closed doors. Consequently, much criticism which is addressed to the EU in total might hold even more true 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 builds up 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 of e.g. the Commission. In contrast, output legitimacy results from 'government for the people', i.e. whenever policies meet the interests of concerned stakeholders. Thus, this kind of legitimacy does not depend so much on the process of decision-making, but on the quality of its final outcome.

A crucial issue for the legitimacy of supranational risk regulation is the relationship between input and output factors. Here, two hypotheses confront each other. On the one hand, the two kinds of legitimacy may be positively correlated, and output legitimacy may result from input legitimacy (e.g. Joerges and Neyer 1997, 2006). According to this argument, the output of policy-making can only be as good as its input. If citizens are able to influence policy-making, they will ensure that the final outcome is in their own interest. Thus, it is necessary to strengthen the input side of policy-making in order to ensure legitimate outputs. On the other hand, the two kinds of legitimacy may be negatively correlated, and high input legitimacy may conflict with high output legitimacy (e.g. Majone 1996, 1998, 2001). According to this view, inputs of stakeholders disturb regulatory policy-making, because stakeholders themselves are trapped between time-inconsistent interests. In the long-run, they all prefer the best possible regulatory policies in order to profit from well-functioning markets, but in the short-run, they might opt for sub-optimal solutions which favour their particularistic distributive interests. In order to avoid regulatory capture by such short-term interests, regulatory policy-making should take place at arm's length from political bodies. Regulators should only be *ex post* accountable to stakeholders to ensure that policy-making does not deviate from their common long-term interests.

This article explores the relationship between input and output legitimacy of supranational risk regulation at the example of the EU regulatory regimes for pharmaceuticals and foodstuffs. It starts with operationalising variables which stand for high input and output legitimacy. Whereas input legitimacy depends on the process of policy-making, output legitimacy results from the fact whether supranational regulatory regimes are able to achieve their policy objectives. Thereafter the two competing hypotheses are elaborated 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 to restore consumer confidence. Thus, the article concludes that the two cases support the hypothesis of a trade-off between input and output legitimacy, and that the latter is more important for risk regulation than the former.

2. Legitimising Factors of Supranational Risk Regulation

The potential legitimacy deficit of the EU has bothered the academic discussion to an immense degree within 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. A broad range of scholars see member states as the main source of legitimacy within the EU (Moravcsik 2002, Joerges and Neyer 1997). Another view is that the EU suffers from a democratic deficit, because the EP is too weak and does not elect the executive (Crombez 2003, Follesdal and 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 the four approaches are not compatible with each other. 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 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 for this article 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 the member states?

2.1 Input Legitimacy: Member States, European Parliament and Stakeholders

The most convincing argument why the EU should rely on the member states as the main source of legitimacy is surely 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 identity and solidarity should allow 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 solution would be that decisions have to be based on consensus of all member states in order to be legitimate. Qualified majority voting in the Council and participation of the EP would increase the legitimacy deficit rather than reduce it. Majority rule in the Council would allow that some Member States are overruled, and that citizens of these member states cannot hold their governments responsible for such decisions. And increasing influence of the EP would even reinforce 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 missing. Such redistributions are zero-sum games, where some parties win what other parties lose, 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 redistributive 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 necessity of unanimity 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* as 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 (Jachtenfuchs 1999). 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 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 legislative process surely increases the legitimacy of EU policy-making.

Besides participation of the member states and the EP, a third mechanism to increase input-legitimacy of supranational risk regulation is the participation of 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 that in 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 favours producer vis-à-vis consumer interests even further (e.g. Scharpf 1997). 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 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

The next question is, whether supranational regulatory regimes may provide output legitimacy on their own. Scharpf (1997) is sceptical in this respect, because he regards the EU's potential for positive integration as rather limited. Whereas negative integration is written down in the treaties, positive integration needs to pass 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. However, Scharpf (1996b) himself distinguishes between two kinds of regulatory standards, which are differently difficult to harmonise at 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 EU level, because poorer Member States would lose their competitiveness vis-à-vis richer member states, if social standards would be harmonised. On the other hand, product standards – including most measures of health and consumer protection – are less difficult to harmonise. The member states only 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, supranational regulatory regimes which would help Member States to overcome these coordination problems and to adopt harmonised product standards would in fact increase the output of EU policy-making.

Indeed, supranational regulatory regimes may provide more output legitimacy than individual member state action (Menon and Weatherill 2002). If the member states adopted own regulatory standards for risky products, they would have to choose whether these prevail over other member states' standards, or whether the mutual recognition principle applies. In the former case, the member states would face enormous difficulties to establish the Single Market, because national regulatory standards always constitute non-tariff barriers to trade. Thus, the member states would forgo the efficiency gains, which are inherent in the Single Market and increasing international trade. And in the latter case, the member states would face the danger of regulatory competition where the lowest standards prevail. Thus, the level of health and consumer protection would decline at least in member states with formerly high standards. At least for risky products, the member states would have difficulties to achieve 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 avoid agency drifts and losses of output legitimacy, supranational regulatory regimes should be subject to *ex post* political scrutiny in the long-run (e.g. Dehousse 1999, Everson 1995, Majone 1996b: 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 own interests in an increasing regulation of their sector – either under- or over-regulation might be the result. Three

different addressees of accountability can be distinguished: the EU legislative actors, the member states themselves and the European citizens.

Firstly, the legislative actors usually establish so called Comitology procedures in order to oversee the regimes' day-to-day operation. 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 maybe – if the committee denies its approval – of the Council. Thus, the regimes' expert bodies are dependent on agreements of the Commission and the Council in order that their proposals become 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 regime. It is just 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 accountable to the member states. This accountability is first of all ensured by the aforesaid oversight mechanism in which member state committees and the Council control the regimes' day-to-day policy-making. However, there is also a second and softer mechanism to ensure accountability of regimes vis-à-vis the member states' own regulatory authorities. EU expert bodies could consist of representatives from member states' regulatory authorities, instead of scientific experts from outside. Thus, supranational regulatory regimes would be embedded within networks of national regulatory authorities, and these authorities may scrutinise supranational regimes from a more scientific point of view (Dehousse 1997, Majone 1997).

Finally, supranational regulatory regimes should be accountable to European citizens in general and to the addressees of their regulations in particular. The first precondition for this is that decision-making within regulatory regimes is open and transparent (Dehousse 1999, Héritier 1999, 2003). It is only possible to hold actors within the respective regimes accountable, if it can be followed from outside who takes which decision at which stage in the decision-making process. However,

transparency alone does not help to hold supranational regulatory regimes accountable, as long as citizens cannot challenge regulatory decisions. Here, the European courts – namely the ECJ and the Court of First Instance – get an important role, because they may scrutinise regulatory decisions on behalf of EU citizens.

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

2.3 Input and Output Legitimacy: Symbiosis or Trade-Off?

Two competing hypotheses about input and output legitimacy of supranational risk regulation face each other within the academic literature. Joerges and Neyer (1997, 2006) argue that different social interests should be taken into account in the regulation of the Single Market. Especially the member states are still seen as the most legitimate representatives of their citizens' interests. Consequently, member states' interests cannot be neglected in Single Market regulation. Joerges and Neyer favour the EU committee system as a forum for regulatory policy-making, because it allows the representation and balance of different positions and interests. Scientific and expert committees allow for representation of science, stakeholder committees represent the positions of interests groups, and member state committees allow to represent legitimate national interests. Because the involved actors meet repeatedly within the committee system and because they act before the background of European law, they are supposed not to bargain about their particularistic interests, but to engage in a deliberative search for the most appropriate regulatory policies. The resulting policies are not only deemed to be the most legitimate, but also the most efficient ones, because they are based on the expertise of all involved actors. Thus, the assumption is that input and output legitimacy correlate positively.

In contrast, Majone (1996, 1998) argues that risk regulation should derive its legitimacy not so much from input, but more from output factors. He bases his argument on the assumption that political interests disturb the search for the most adequate regulatory policies. Stakeholders – and consequently also political actors which are dependent on citizens' support – face diverging long- and short-term interests. In the long-run, the whole society has an interest in efficiently regulated markets, which protect consumers adequately before the risks of certain products, but which do not hinder economic activities more than necessary. However, in the short-run, stakeholders might have particularistic interests in regulatory policies. Producers might push for low regulatory standards in order not to endanger their market shares. And consumers might opt for precautionary regulatory policies, if scandals provoke their scepticism. If regulators were captured by such particularistic short-term interests, they would follow the will of a particular group and would not engage in the search for the best regulatory policies anymore – output legitimacy would decline. Thus, the underlying assumption is that increasing input legitimacy – i.e. the representation of political interests – conflicts with output legitimacy.

The following empirical analysis aims to test these competing hypotheses. According to the hypothesis of Joerges and Neyer, one would expect that participation of political actors – member states' governments, the EP and stakeholder groups – leads to efficient supranational risk regulation. Input and output legitimacy should occur at the same time. According to the hypothesis of Majone, one would expect that supranational risk regulation is the more efficient, the more independent the regime is from political interventions. Input and output legitimacy should not exist in parallel.

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 are chosen, because the regulated products have much in common: Both pharmaceuticals and foodstuffs are incorporated by consumers, and consequently, they both might 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 look rather similar on first view, because they are build up around supranational regulatory agencies. Of course, there exist also structural differences between pharmaceutical and foodstuff regulation. As a result of high investment costs, the market for pharmaceuticals is relatively homogeneous, and pharmaceuticals can thus be subject to pre-marketing control. In contrast, most kinds of foodstuff are only subject to post-marketing control in Europe, i.e. regulatory authorities only react, if problems with foodstuffs are detected, but they do not control every food before it gets access to the Single Market. It is obvious that such differences have to be kept in mind for a comparative analysis (see also Krapohl 2004, 2007).

3.1 The Case of Pharmaceuticals

3.3.1 Input Factors

Regarding input legitimacy, two imbalances can be observed during the whole development of EU pharmaceutical authorisation. Firstly, the establishment of a single market for medicinal products was clearly a project of the pharmaceutical industry. After mutual recognition of national marketing authorisations failed to create such a market (Feick 2002), industry pushed actively toward the centralisation of pharmaceutical authorisation in the EU. And secondly, intergovernmental legitimacy was always much stronger than supranational legitimacy. The whole regime was established by the Commission and the Council with little influence of the EP. As a result of these unbalances, the overall input legitimacy of the EU regulatory regime for pharmaceuticals can be regarded as relatively weak – a fact which changed only little during the latest reform at the beginning of the new millennium.

The interests of pharmaceutical producers can be much easier organised and articulated than that of patients (Abraham and Lewis 2000: 44-49). The reasons for this are obvious: Producers constitute a small group of actors, their interests in pharmaceutical (de-)regulation is very concrete, and they own much resources for lobbying. In contrast, consumers constitute a much larger group, their interests are

much more diffuse, and they have less resources to spend. This imbalance of strength distinguished the development of the EU regulatory regime for pharmaceuticals. The establishment of a single market for pharmaceuticals and of a respective supranational regulatory regime was mainly a result of lobbying by the pharmaceutical industry. 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 and 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 consultation procedure, 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 of producer and consumer interests 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 and Andersen Consulting 2000). To get such an assessment, an extensive survey among all stakeholders in the field was conducted. As a result of the wide spectrum of addressees, the report was supposed to be balanced between different social interests. However, an overwhelming part of the report deals only with issues which are important for the pharmaceutical industry. Thus, even if the authorisation system was positively evaluated by consumers, the input of the two different groups of stakeholders remained rather asymmetric.

The asymmetric influence of consumer and producer interests during the establishment and reform of the EU regulatory regime for pharmaceuticals is mirrored within its day-to-day operation. As applicants for marketing authorisations, applying companies have privileged access to the regime (Abraham and 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 and 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, chances to influence the regime's day-to-day decision-making are asymmetrically distributed.

During the establishment of the regime, the Commission and the Council were the crucial legislative actors, whereas parliament's influence was very limited. At the beginning of the 1990s, the regime was established within a consultation procedure. Within that procedure, the Commission and the Council were not bound by opinions of the EP (Tsebelis and 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 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 and Feick 2005). Within such a co-decision procedure, legislative proposals need the approval of both legislative actors – by an absolute majority of EP members and a qualified majority within the Council – in order to come into force. Now, both the EP and the Council stand on equal footing and are equal legislators (Tsebelis and 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 reduced. Consequently, the overall level of input legitimacy was somewhat higher for the latest reform than for the original establishment of the regime.

The strength of the member states and the weakness of the EP during the initial set up of the regulatory regime is reflected within its institutional architecture (Kelemen 2002). On the one hand, 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. Thus, intergovernmental legitimacy of the authorisation process is relatively strong. On the other hand, 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, the regime cannot justify its decision-making on any supranational input-legitimacy, which may derive from participation of the only directly elected EU body. In sum, 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.

To conclude, the overall input legitimacy of the EU regulatory regime for pharmaceutical is rather low and imbalanced between different actors. Both the establishment of the regime and its policy-making are dominated by input from the pharmaceutical industry and the member states. Thereby, the legitimising potential of consumer groups and of the EP is missing. According to Joerges and Neyer, one would expect that the regime's output legitimacy is also low. However, according to Majone, the regime could still produce output legitimacy, as long as it is able to act independently from the interests of producers or the member states.

3.1.2 Output Factors

In comparison to input-legitimacy, output-legitimacy of the EU regulatory regime for pharmaceuticals is relatively high. The regime is made responsible for its policy-output to a range of actors. The 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-one controls the regime, the regime is nevertheless under control (Moe 1987). As a result, the efficiency of the supranational regulatory regime is quite high. Despite the asymmetric influence of producers and consumers, the wide-spread hypothesis of a one-sided capture of the regime by industry's interests (e.g. Abraham and Lewis 2000) lacks empirical support. On the contrary, the various controls inherent in the system seem to counterbalance the disproportionate influence of industry (Gehring and Krapohl 2007).

Firstly, within the centralised authorisation procedure, the regime is predominantly responsible to the Council and the Commission. Large majorities of the agency's management board and expert committee are directly recruited by the member states. Besides, the Council and the Commission may both directly control the regime during the Comitology procedure. The Commission is formally free, whether it accepts scientific opinions of the agency within its policy proposals. And the member state committee could reject the Commission proposals, in which cases matters would be referred to the Council. The Council would then have the final say on the authorisations of medicinal products. Within this political phase, the supranational regime is accountable to the Commission and the Council in the short-run, because both can intervene directly in its day-to-day operation. However, as the empirical analysis of the centralised procedure demonstrates, the Commission and the Council usually do not use this control mechanism (Krapohl 2005: 105-132). 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 within day-to-day decision-making of the regime.

Secondly, the regime is also accountable to the national regulatory authorities for pharmaceuticals. Within the centralised procedure, this 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 authorities, and need the scientific resources of their national authorities in

order to evaluate applications for marketing authorisations. Within mutual recognition, accountability is reached via the acceptance of national authorisations by the regulatory authorities of other member states. Therefore, the concerned member states' authorisation bodies have to trust the scientific evaluations of the reference member states' authorities. To sum up, the national authorisation bodies for pharmaceuticals establish a regulatory network either inside (centralised procedure) or outside (mutual recognition) the European agency (Majone 1997). Within this network, all experts of the national authorities 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.

Finally, the supranational regulatory regime has to justify its decision-making vis-à-vis the European people, including producers and consumers of pharmaceuticals. Here, it is often criticised that the regime operates very much in secrecy (Abraham and Lewis 2000: 172-201). Applications for marketing authorisations contain information, which are intellectual property of the applying companies, and which constitute important competitive advantages for them. If information about new pharmaceuticals would become public during the authorisation process, pharmaceutical companies would lose their competitive advantages. It is evident that the intransparency of the regulatory regime favours the interests of producers vis-à-vis that of consumers. As applicants for marketing authorisation, producers have privileged access to information, whereas consumers have to scrutinise regulatory decision-making from outside closed doors. Nevertheless, the extensive legalisation of European pharmaceutical authorisation and a relatively wide scope of plaintiffs lead to potentially strong judicial review of the supranational regulatory regime. Producers of pharmaceuticals may always challenge (negative) authorisation decisions, because these are directly addressed to individual companies and influence their legal positions directly (Collatz 1996: 143-146). One problem is that access to European courts is asymmetrically distributed among stakeholders. Consumers are usually not individually and directly concerned by authorisation decisions, and consequently, they may have some difficulties to bring

claims against authorisation decisions in front of the European courts. Here again, the interests of consumers are disfavoured against that of producers. However, one has to take in mind that the EU organs and the member states are always entitled to bring claims in front of the ECJ. Thus, they could step in, if they see their consumers' health endangered by authorisations of specific products (Gehring and Krapohl 2007).

Despite some asymmetries in the accountability of the regime, this dimension of output legitimacy is in sum relatively strong. The regime is held responsible by three mechanisms: Firstly, it is politically controlled by the Commission and the Council within the Comitology procedure; secondly, it is embedded within a regulatory network; and thirdly, it is subject to strong judicial review by the European courts. It is important to state that not a single 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 had to capture all three of these mechanisms – a task which shall be extremely difficult also for the strong pharmaceutical industry.

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 that of consumers (e.g. Abraham and Lewis 2000, Feick 2005, Permanand and Mossialos 2005). Firstly, it is argued by critiques that 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 and Lewis 2000: 147-168). In order to attract applications (and application fees), regulatory authorities might be tempted to lower their evaluation standards. And secondly, critiques assume that pressure for fast approvals of pharmaceuticals leads to less in-depth scrutiny of products by regulatory authorities (Abraham and Lewis 2000: 147-168). However, the effects of a regulatory competition and a pressure towards fast approval times are countervailed by the reputation mechanism within the regulatory network (Majone 1997). Within the centralised procedure, the members of the expert committee need to be appointed as

rapporteurs by their peers. And within the mutual recognition procedure, the reference member states' initial authorisations have to be accepted by the concerned member states. Thus, the national regulatory authorities need good reputation among their neighbours. It is doubtful that it pays off for regulatory authorities to lower their standards systematically under these conditions, because they would thereby damage their reputation.

As an evaluation report – which was conducted on behalf of the Commission at the beginning of the millennium – indicates, both producers and consumers seem to be satisfied with central features of the EU regulatory regime for pharmaceuticals (Cameron McKenna and 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 consumers' 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 would systematically be 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.

To conclude, the output-legitimacy of the EU regulatory regime for pharmaceuticals is high. The regime is accountable to a whole range of actors via several control mechanisms. Although the EP and consumer interests are somewhat disfavoured, there is some evidence that the control mechanisms prevent systematic capture of the regime by industry's interests. As a consequence, the problem-solving capacity of the supranational regulatory regime is high. Whereas industry's interests in centralised market access are clearly served, also consumers' interests in high

regulatory standards seem to be well protected, and both groups of stakeholders expressed their satisfaction with central features of the regime.

3.2 The Case of Foodstuffs

3.2.1 Input Factors

In contrast to the pharmaceutical sector, the new EU regulatory regime for foodstuffs is not an industry project, but it was established as a reaction to consumer concerns after the BSE scandal. Before the 1990s, i.e. before the BSE crisis, the old regime consisted of a range of scientific and member state committees. These committees were hardly legitimised by input of the EP or by a balanced selection of interests groups. Instead, decision-making was predominantly intergovernmental and served the interests of producers in a single market for foodstuffs. However, the situation changed, when the BSE scandal raised the attention of consumers. During the latest reform of the regime, the EP was very powerful and represented to a large extent the diffuse interests of European citizens. As a result, the input-legitimacy of the new regime is much higher than that of the old one.

After the British government had to announce in 1996 that BSE might endanger the health of consumers, the EP became very active (Westlake 1997). It 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, if this would not follow the recommendations of the inquiry committee (European Parliament 1997). On its advice, the Commission immediately reorganised the committee system in the foodstuff sector, established a Food and Veterinary Office, and concentrated the relevant competencies in the DG for Consumer Policy and Health Protection. 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 into 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, which was adopted after 1997 – i.e. the set up of the European Food Safety Authority (EFSA), the establishment of a general food law, and the reform of the genetically modified food (GM food) regime –, the EP and the Council were equal legislators (Tsebelis and Garrett 2000, 2001). Thus, input-legitimacy increased significantly 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 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. And secondly, the EP successfully represented the diffuse interests of consumers within the legislative process (Kelemen 2002, Pollack 1997). From 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 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 has 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 consequence of the recruitment of the management board and of regular stakeholder consultations, the new regulatory regime for foodstuffs can be accessed much easier than the old one.

To conclude, input legitimacy of EU foodstuff regulation increased significantly 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 on 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. As a result, both supranational and transnational input-legitimacy of the EU regulatory regime for foodstuffs became much stronger.

3.2.2 Output Factors

As the crisis of consumer confidence (Ansell and Vogel 2006, Majone 2000, Vogel 2001a) in the foodstuff sector indicates, the output-legitimacy of EU foodstuff regulation is extremely weak. The BSE crisis of the 1990s and ongoing critique of GM food authorisations damaged consumers' trust in the quality of their food and the regulatory competence of the responsible EU bodies. In the following, this section analyses the weak output-legitimacy in more detail. Firstly, it evaluates the policy-output of the regime during the last twenty years. It becomes obvious that this policy should neither please consumers nor producers of foodstuffs. And secondly, the section scrutinises the institutional mechanisms, which hold the new regulatory regime accountable to its different principals and stakeholders. The question is, whether these accountability mechanism are strong enough to bring the regime back on track within the coming years.

The policy-output of the EU regulatory regime for foodstuffs obviously does not meet the interest of stakeholders. During the BSE crisis, European consumers were

not cleared up 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 and Zurek 2006). In the light of 14 years of insufficient protection against the new cattle disease, consumers mistrust in the EU institutions becomes 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 2001b), but which met heavy scepticism of European consumers (Ansell, Maxwell and Sicurelli 2006). In reaction to consumers mistrust in these new foodstuffs, the member states adopted a de facto moratorium against GMOs and GM food. They blocked the authorisation of further products within the Council, and used their safeguard competencies to ban already authorised products from their national markets. 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 are 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 only. But in 2000, when BSE was detected in most European countries, the whole Single Market was disturbed. Beef disappeared from the menus of public canteens and from the Christmas meals all over Europe. Consequently, demand and prices for beef collapsed. The situation is similar, although less dramatic, in the case of GM food. Even if producers get their GM food authorized by the Commission, they still have to label their products as such. Due to skepticism of consumers, the demand for such products in Europe is very low. Producers are dependent on consumers' confidence in the safety of their products in order to distribute them successfully in the Single Market. Besides, the ongoing political disputes about GMOs and GM food lead to a high degree of uncertainty for producers. It is unsure, whether a market for such products will emerge, and whether investments will pay off in future. Producers would profit from a more efficient regulatory regime for foodstuffs in two respects. On the one hand, such a regime would regain the confidence of consumers, and this confidence is extremely

important for a stable demand for certain foodstuffs. On the other hand, a more stable regime would lead to less uncertainty for producers, and they would face less risks when investing in certain foodstuffs.

In order to bring the regulatory regime for foodstuff back on track, it is important that principals and stakeholders are able to hold the regime responsible for its action in the long-run. First of all, the regime should be 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 other two legislative actors, within a Comitology procedure. Therein, the Commission is always free, whether it follows the advice of the agency in its own policy proposals, and the member states can amend or reject Commission proposals within a standing committee and finally within the Council. Thus, both the Commission and the Council can 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 the member states, which are the principals of the whole EU. Here, one may distinguish two different mechanisms. On the one hand, the regime is responsible to political bodies of the member states, most notably the national governments. These are represented within the Comitology committees and the Council, and thus, they have to vote on every policy-proposal before it gets adopted. On the other hand, the regime could also be accountable to the regulatory authorities 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 authorities for foodstuffs, and thus, it follows the example of the expert committee of 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 within the crucial phase of decision-making. In contrast, the Advisory Forum in the

foodstuff sector has no formal decision-making competencies. It just 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. As a result, scientific disputes between different regulatory authorities become more easily politicised.

Finally, the foodstuff regime should as well be responsible to the European citizens themselves. In order that citizens can hold the regime accountable, its decision-making must be transparent and subject to judicial review. Concerning the first condition, one has to assess that the regime is rather transparent. During and after the BSE crisis, many efforts were made to open the regime to public scrutiny. Today, nearly all information about the regime's decision-making are published and can be easily accessed on the Internet. However, concerning the second precondition, 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 that decisions. Stakeholders which are affected by broader regulatory policies have more difficulties to demonstrate their direct and individual concern, if they want to bring claims in front of the ECJ or the Court of First Instance. The only exception from 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. Although regulatory policy-making is transparent enough to be monitored by the public, there are little chances for stakeholders to challenge regulatory decisions judicially. Consequently, opposition to the regime can only be expressed politically. Stakeholders may lobby against regulatory decisions at their national governments or the Commission, which may then try to hold the regime accountable. But, this carries the danger that conflicts about regulatory policies become politicised.

Although some of the accountability mechanisms are very strong, they are in sum very unbalanced. The regime can be easily held responsible by the Commission and 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 against the regime has always to take the political route, and thus, conflicts are always endangered to become politicised. If national experts disagree with a scientific opinion of 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 at their national governments or the Commission. 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.

To conclude, the output-legitimacy of the EU regulatory regime for foodstuffs has been very weak during the last 15 to 20 years – and it is unlikely that this fact will change in the future. The BSE crisis and the ongoing disputes about the authorisation of GMOs and GM food have destroyed consumers' trust in the safety of their food and in the policy-making of the regime. Neither consumers, nor producers can be satisfied with this result. The supranational regime has so far not been able to establish a sustainable level of health and consumer protection, which would meet the long-term interests of both groups of stakeholders. It is still an open question, in how far EFSA will contribute to an improvement of the situation, but one may cast some doubts in this respect. The sector is still very much politicised, and convergence between consumers' and producers' expectations is out of sight.

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 derives its legitimacy mainly from output factors, whereas input legitimacy is rather weak. 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, and overall input legitimacy remained rather weak. 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 builds up on input legitimacy, whereas output legitimacy is 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 Commission and 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 proves able to restore consumers' confidence, which was lost during the BSE crisis and the ongoing disputes about the authorisation of GM food.

The negative correlation between input and output legitimacy clearly supports the hypothesis of Majone vis-à-vis that of Joerges and Neyer. According to the latter, strong output legitimacy should result from strong input legitimacy. Thus, 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 thus 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 its tasks much better than the politicised foodstuff regime. Thus, the pharmaceutical regime might be undemocratic in regard to its input, but it meets nevertheless acceptance from citizens due to its strong output. In contrast, the foodstuff regime might be more democratic, but it is not able to restore consumers 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 Commission, the EP and the member states – within the day-to-day operation of the regime should be reduced. The regime should become more independent, more legalised and more judicialised. In order to replace the resulting lack of input legitimacy, more accountability mechanisms should be introduced. Experts from member states regulatory authorities for foodstuff should be able to challenge the regimes decisions without taking the long 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 like in the pharmaceutical sector would emerge, wherein no one directly controls the regime, but the regime is nevertheless under control (Moe 1987).

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