commercial wares. Thus, the various interests that inform the shape and substance of market regulation -- ranging from competitiveness, innovation, and market stability and fairness, to worker, consumer, and environmental protection -- collide in chemical risk decision-making in a highly visible and explicit way.[1] Finally, since the EU regulatory framework for the production, marketing and use of chemicals has recently undergone a major overhaul, it offers a good insight into how and the extent to which notions of inclusiveness are currently being integrated into governance of the European market.

The analysis will show that, formally at least, the EU regulatory regime for chemicals control is far more inclusive than its predecessor. However, when looking below the surface of formal arrangements, and particularly taking into account that the effectiveness of inclusion is determined not only by the creation

the EU market after September 1981 or 'new substances'. The latter distinction was mostly the result of political and economic expediency. As awareness grew throughout the 1970s that the availability of timely and reliable information concerning the health and environmental impacts of the release of chemical substances was crucial for the design of a risk management framework that had a


Law

As is already apparent from even a snapshot overview, the old regime was institutionally dominated by public authorities, in the first place national regulatory authorities (NRAs). NRAs administered the notification process, performed risk assessments for new substances and, as rapporteurs, fo

EVALUATION[22]

The data gathering requirements under REACH connect to the framework's second risk management stage: the evaluation procedure. Evaluation covers the evaluation of dossiers submitted pursuant to registration, which is compulsory for


Law

orchestrates the scientific review of the technical file and risk assessment

INCLUSIVE GOVERNANCE IN REACH

As a prominent strand of the pervasive discourse on 'good governance' which has so dominated the last ten years of EU regulatory studies, the most commonly understood version of inclusive governance focuses on the question of how, and to what extent, different stakeholders get to represent their interests and participate in the process of law- and decision-making.[34] For reasons that have been thoroughly discussed elsewhere, attention tends to centre around those stakeholders and interests that, although affected by regulatory processes and their outcomes, traditionally had very limited opportunities for direct engagement.[35] Often, such categories of stakeholders are loosely grouped under denominations such as 'the public', 'the public interest', or 'civil society' -- terms which all construe oversimplified but workable representations of those entities that do not have a privileged status in regulatory decision-making by virtue of authority or specific designation in the regulatory framework.

The analysis below follows this format as it looks at opportunities for private stakeholders, and particularly stakeholders that are not the direct addressees of the regulatory prescriptions in the REACH Regulation, to be involved in the regime for chemical risk control, in terms of its development (input), its operation (throughput), and vis-à-vis the decisions it generat

Preparations;[38]

THROUGHPUT

A key question in examining the inclusiveness of the REACH framework inquires into the extent to which different interests and stakeholders are represented in decision-making pursuant to REACH. As indicated before, REACH comprises a range of decision-making procedures, going from procedures to determine whether a registration is complete, and hence whether a registration number can be assigned which validates a product's new or continued circulation on the EU market, to the identification of highly dangerous chemicals that should be authorised, the authorisation itself, and the adoption of risk reduction measures for substances that are not subject to authorisation but nonetheless pose unacceptable risks. To gain a preliminary insight into the level of inclusive risk governance under REACH, this paper focuses on the interplay between institutions and interests taken into account in the authorisation process of a substance identified as falling under the authorisation requirements. Admittedly, authorisation constitutes but one pillar of the REACH framework; a complete picture of the organisation and degree of inclusiveness of the contemporary EU chemicals control regime, as an example of modern risk regulation, would additionally require the consideration of consultation and participation provisions in the registration, evaluation, authorisation identification, and risk reduction processes. However, since selectiveness cannot be avoided within the confines of a paper, the focus on the authorisation process is warranted because this process involves the marketing and use of precisely those chemicals that generate the highest level of public concern. Consequently, authorisation is the regulatory process in which the public arguably has the strongest interest in participating, and where exclusion from decision-making is least justifiable. The authorisation procedure therefore is a good indicator of the degree of inclusiveness aspired to under REACH, and of the likelihood of effectiveness.

Agency (EFSA).[51] Thus, at first glance the review stage of the authorisation process should be heavily technocratic, dominated by a group of independent, unelected civil servants located in the beautiful but rather remote Helsinki. However, to represent the review stage as purely technocratic, and in the hands of one monolithic institution, rather underplays the complexity of the review process for two reasons.

First, it does not take into account the checks and balances built into the authorisation process. Once an application is submitted to ECHA, it forwards the application dossier to its Committee for Risk Assessment (CRA) and its Committee for Socio-Economic Analysis (CSEA) to produce a draft opinion within 10 months of submission. Consultation with 'third interested parties' is foreseen in Article 64(2) of the REACH Regulation. Beyond this provision, CSEA can ask either the applicant or third parties to give additional information on


Law

step towards inclusiveness. However, we do need to be aware of the Regulation's

sheets as a precondition to registration. Thus, contextual factors pertaining to the use and anticipated or known exposure of a substance become attached to and can influence the initial risk identification process. The need to contemplate use and

environmental impacts.[75] More robust assessments generally require a combination of testing, epidemiological studies and monitoring mechanisms.[76] On the latter aspects, REACH is particularly weak. It is interesting to observe that the critiques on the effectiveness of the data gathering provisions for environmental risk control are not new; they have been around since well before the 1998 review.[77] However, in contrast to the criticism on the expediency of the former regulatory framework to deliver regulatory outcomes, they were not included or addressed in the reform process.

partial scope for ex-post scrutiny. On balance, this is a reasonably good scorecard from the point of view of inclusive governance.

However, a contextual appraisal does indicate that th