Summary

Increasingly, the notion of 'meta regulation' is being seen as an alternative to the classical vertical model of government regulation which has always focused on results (outputs and outcome). Classical vertical government regulation focuses on the questions of whether certain defined norms are being deviated from, whether permit holders are meeting their obligations, and whether a certain minimum level of quality is being attained. Meta regulation, on the other hand, focuses not so much on outputs and outcomes, but more on the business processes and strategies which lead to those outcomes, and the internal procedures within companies or sectors which ensure compliance with rules and standards. In order to understand how meta regulation works and under which conditions meta regulation can provide a suitable arrangement for carrying out governmental regulation, this study will address the following question:

- *Under which contextual and institutional conditions is meta regulation a suitable arrangement for carrying out governmental regulation and how does meta regulation work in practice?*

The following sub-questions have also guided this research:

1. What is the administrative and societal background against which the rise of meta regulation needs to be understood?
2. What is meta regulation, and how does it differ in ideal-typical terms from vertical product regulation?
3. To what extent does the set-up and functioning of meta regulation differ from that of classical vertical governmental regulation in various sectors?
4. What are the effects and side effects of meta regulation in the cases researched here?

Structure of the research

Using the definition of the *Inspectieraad* (the General Inspectorate of the Netherlands) as a basis, we define meta regulation as follows: *"Meta regulation is regulation which specifies the set-up, scope and functioning of (quality) systems and business processes within organisations. This is done by means of audit-style inspections and reality checks."* In accordance with the *Algemene Rekenkamer* (Netherlands Court of Audit) (2008), we expand this definition in the sense that meta regulation is vertical regulation in which the authority makes use of existing internal assurance systems within organisations or sectors. In this research, we focus specifically on quality control systems and risk management systems, or 'safety management systems'. Our research can be characterised as administrative-

sociological. We view the set-up and functioning of governmental regulation as a part of a sector's administrative arrangements and we have asked ourselves to what extent and under which conditions organisations in the six sectors we analysed are able to regulate themselves and establish and maintain internal assurance systems. We then examined how meta regulation in these sectors works and its impact on the collection of information, the testing framework and the ability of the regulator to influence behaviour. For the empirical research, a total of six sectors were selected in which meta regulation would appear to be present. These were as follows:

1. Inspectorate of the Ministry of Transport and Water Management (*Verkeer en Waterstaat*), specifically their work regulating air traffic;
2. State Supervision of Mines (*Staatstoezicht op de Mijnen*).
3. The *Autoriteit Financiële Markten* (Financial Markets Authority), specifically their work regulating the provision of financial services provision by large financial institutions;
4. The Food and Consumer Product Safety Authority (*Voedsel en Warenautoriteit*), specifically their work regulating the meat-processing industry;
5. The *Inspectie van het Onderwijs* (Education Inspectorate), and specifically the regulation of pre-school and early school education;
6. The *Inspectie Gezondheidszorg* (Health Care Inspectorate) and specifically the certification for Harmonised Quality Assessment in the Health Sector (*Harmonisatie Kwaliteitsbeoordeling in de Zorgsector*) in mental health care.

The six sectors that we analysed differ in terms of the primary risks that need to be guarded against, the societal impact of those primary risks, and the administrative relationships that characterised the sectors. In the education and mental health sectors, it is implementation that is subject to regulation, while in the other four sectors compliance is subject to regulation.

Question 1: How can the rise of meta regulation be understood?

In order to understand the rise of meta regulation, we first of all reconstructed the rise and development of meta regulation in official memoranda, recommendations and within the *Inspectieraad* (the General Inspectorate of the Netherlands) (chapter two). From 1998 onwards, successive cabinets worked on a general framework for governmental regulation of executive organs and bodies. In two *Kaderstellende Visies op Toezicht* (Whitepapers on Regulation), the principles of good regulation were developed. In the first Whitepaper on Regulation of 2001, the emphasis was on the legitimacy of governmental regulation. Governmental regulation was required to ensure conformity to certain standards of independence, transparency and professionalism (Whitepaper on Regulation, 2001). In the Second Whitepaper on Regulation of 2005, in addition to the legitimacy of regulation, the effectiveness of regulation was emphasised. To reduce the burden of regulation, it was recommended that governmental regulation should become more selective and nimble-footed, and that there should be more cooperation between regulators (Whitepaper on Regulation, 2005). This emphasis on effectiveness was part of a government-wide drive to reduce the overall administrative burden. Within the *Inspectieraad* (the General Inspectorate of the Netherlands), within which all regulators are represented, ever more attention is being given to meta regulation as a means of satisfying the demands for legitimacy and effectiveness. On the basis of policy reconstruction, we note that a general policy theory of meta regulation is indeed being developed within governmental regulation. In various official memoranda, it is being recognised that meta regulation depends to a great extent on the self-regulatory capacity of the regulatees. However, the expectations surrounding meta regulation remain high. For example, it is expected that meta regulation will lead to a greater capacity for learning on the part of regulatees and that meta regulation will indeed lead to a reduction in the regulatory burden for businesses and institutions.

Question 2: What is meta regulation?

In meta regulation, the focus of the regulator is on evaluating and monitoring the functioning of internal assurance systems. Ideally, the regulatee will monitor whether its own rules and standards are being attained through its own internal assurance system. Internal assurance systems can focus on controlling potential risks with negative external effects (such as security-related, economic or environmental risks) or on maintaining a minimum level of quality. In the conceptual theoretical analysis of meta regulation in chapter three, we address the question of which conditions could potentially impact on the effectiveness of meta regulation. We define three sectoral conditions which are of relevance: the primary risks which must be guarded against in the sector; the social and political perception of those risks; and the self-regulatory capacity of the regulatee. These self-regulatory capacities involve a high degree of responsibility for actions taken and competence over the actions taken on the part of the regulatee. We assume that these, in turn, are related to the constellation of interests and dependency relationships between the actors that are involved with a given risk. Additionally, we also examine what meta regulation could mean for the way in which information is gathered, the implementation of standards and the capacity of the regulator to influence the behaviour of the regulatee.

Question 3: How does meta regulation function in various sectors?

We conducted empirical research into how meta regulation functions in six sectors, in order to establish what type of risks and dependency relationships exist in the various sectors. In air travel and mineral extraction, the risks are technologically complex and there is a complex chain of dependencies. Were any accident to occur, the direct impact on those involved (the personnel, passengers and the organisation) and the social impact would be considerable. A great deal of specialist knowledge is necessary in order to detect and control the risks in the these sectors. In the meat sector and the financial service provision sector, risks mainly involve the impenetrable and often complex market relationships. Both of these sectors differ from air travel and mineral extraction in that any accident would not necessarily have any direct physical consequences for the perpetrator of the risk or the risk taker. However, there would of course be economic consequences and damage to the reputation of those involved. In pre-school and early-school education and the mental health sector, quality (and therefore the regulation of executive bodies) seems to be difficult to operationalise as a concept. In the case of pre-school and early-school education, another factor is that this is a provisional programme which is difficult to test. Both these sectors are also characterised by the fact that they only involve certain groups.

In technologically advanced sectors such as air traffic and mineral extraction, thinking in terms of systems and systems of dependency is deep rooted. In both sectors, internal assurance systems are also organised unambiguously and authoritatively within each organisation. In other sectors, thinking in terms of systems of dependency is a relatively new phenomenon and creating a clearly delineated system is complicated. In financial services provision, creating a clearly delineated system seems to conflict with the way the market is structured, since it consists for a large part of small, independent intermediaries. In the meat sector, the current problem is that there are many different internal assurance systems. In pre-school and early-school education, it is almost impossible to speak of any system at all and there are doubts about whether it will in fact be possible to make pre-school and early-school education into the 'front door' of primary education. Within the mental health sector, it is striking how relatively unpopular thinking in terms of systems is. The professional autonomy of the doctor providing treatment has long been the organising principle within this sector.

As far as the regulator is concerned, the art of meta regulation is to make the regulatee responsible for complying with and upholding standards. Meta regulation is therefore useful when there are objectifiable standards which can be operationalised clearly and without ambiguity. That is by no means always the case. In pre-school and early-school education and the mental health sector for example, establishing an objective concept of quality has proved difficult. In financial service provision, too, there is discussion concerning what exactly constitutes 'good' service provision. In situations where risks are still unknown and standards have yet to be established, thematic regulation can play a role in detecting those risks and regulating them according to objectivised standards.

The concept of a 'just culture', as used in air traffic, appears to capture rather aptly the nature of the ideal regulatory relationship within meta regulation because it includes the idea of granting privileges. A 'just culture' means that both parties (the regulator and the regulatee) expect to be treated justly by the other. In more concrete terms, this basically means that more openness on the part of the regulatee will be rewarded with trust and less harsh sanctions, provided there is no question of negligence or deliberate wrong-doing.

Question 4: What are the effects and side-effects of meta regulation?

Meta regulation has given rise to great expectations. If the quality of self-regulating quality-assurance systems and risk-management systems within a specific sector could be relied upon, the government would be less reliant on classical vertical regulation. In that way, effective regulation could be carried out using less regulatory capacity. On balance, though, we cannot speak of a reduction in the burden of regulation as a result of meta regulation. What we can identify is a shift in the regulatory burden from regulator to regulatee. It has also become clear that the costs involved in developing and maintaining meta regulation are high. Risks need to be inventorised and analysed; practical and reliable procedures need to be developed. Neither can meta regulation be implemented without reality checks, even in situations where internal assurance systems have already shown convincingly that they are effective. Ever changing internal and external circumstances mean that internal assurance systems must be continually monitored and re-evaluated by external regulators.

This makes meta regulation a knowledge-intensive and labour-intensive form of governmental regulation. However, meta regulation does produce a learning effect. Meta regulation stimulates the development of knowledge of the processes involved in production and service provision, of how the various links in the production chain depend on one another, of how markets function, and of whether policy agendas are effective.

Central question: under which conditions is meta regulation a suitable arrangement?

Our conclusion is that the applicability of meta regulation depends on the dependency relationships and the constellations of interest among the actors involved with the risks to be managed. When the regulatee has a direct interest in managing a risk, such as in air traffic or mineral extraction, that is when there is the greatest chance of self-enforced regulation and reliable, effective internal assurance systems. In the table below, we summarise the relationship between self-enforced regulation and the quality of internal assurance systems.

Motivation for self-enforced regulation:	
Possibility of externalising risks:	When the negative effects of risks are easier to externalise, the motivation for self-enforced regulation will decline (§4.4).
Distance between risk-taker and the effects of the risk:	When the distance between the risk-taker and the effects of the risk is greater, the motivation for self-enforced regulation will decline (§4.4).
Complexity and transparency of the market:	When the market is more complex and less transparent, the motivation for self-enforced regulation will decline (§4.3).
Level of mutual dependence within the system:	When the (perceived) dependence of the actors is greater, the motivation for self-enforced regulation will increase (§4.5).
The quality of internal assurance systems:	
Clear delineation of the system:	When a substantial part of the system does not fall under the scope of the internal assurance system, the usefulness of the assurance system will decline (§5.2).
Internal organisation of the assurance system:	When the assurance system is not organised unambiguously and authoritatively within the organisation of the regulatee, the reliability of the system will decline (§5.2).
Risk analysis and risk indicators:	When the discrepancy between risk analysis and risk indicators is greater, there will be a greater risk of false security and the usefulness of the assurance system will decline (§5.4).
Objectifiability of standards:	When norms can be objectified easily, there will be a higher probability of using an internal assurance system (§5.4).

The presence of a certain degree of organisational and self-regulatory capacity in a sector or organisation is a minimum requirement for meta regulation. Those conditions are by no means present everywhere, as we have been able to establish through this research. But meta regulation can make sense even under sub-optimal conditions. When it can be expected that a certain degree of organisational capacity will be present, meta regulation leads to further learning, both on the part of the regulatee and the regulator. The main added value of meta regulation is that it affords the authorities a better understanding of the dependency relationships and the constellation of interests which surround the risks to be managed.