

## **Administering a Chill Pill? Better Regulation and the Potential for Regulatory Chill in European Union Health Policy**

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This article, which traces the pathways by which the EU Better Regulation agenda creates regulatory chill within the health policy arena, was published in the *Journal of Health Politics, Policy and Law* in 2024 (volume 49, issue 5).

### Abstract:

The European Union's "good governance" program, known as Better Regulation, seeks to improve the quality of EU legislation by controlling the policymaking process. Despite its importance, it is rarely accounted for in the EU health policy literature. Seeking to address this gap, this article introduces Better Regulation in the context of health policy making. It conceptualises a model of regulatory chill, drawn from the literature on international trade, to interrogate the impact of Better Regulation on EU policy-making processes. Using examples from the literature and data from a series of interviews with EU officials, it explores potential pathways of response and anticipatory chill, identifying direct enforcement of Better Regulation, its utilisation by corporate actors, interpretation of its provision by officials, and feedback loops as possible routes of influence. The article argues that such an approach not only presents methodological challenges but also offers a valuable way of conceptualising the relevance of political institutions in general, and Better Regulation specifically, for health. As part of broader calls for attention to the political determinants of health, the article's findings highlight the particular, and often overlooked, importance of metaregulatory policy frameworks.

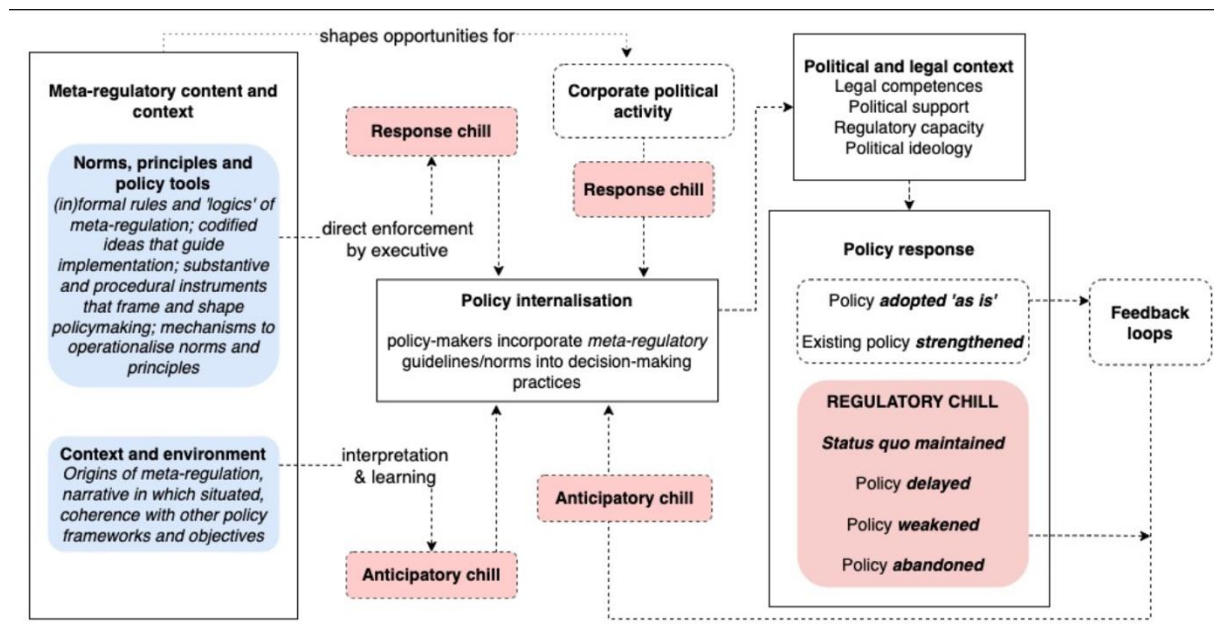
### Introduction to Better Regulation:

- The European Union (EU) Better Regulation agenda aims at improving the quality of EU legislation by strengthening the evidence base, increasing stakeholder participation in policy making, and reducing regulatory burden for businesses and citizens. It is therefore considered a good governance programme. Such programmes are recommended by the Organization for Economic Cooperation and Development (OECD) as a way to promote national welfare and economic growth.
- The effects of Better Regulation have been referred to, by academic and civil society observers, as "regulatory chill" on policy-making processes. This term comes from the literature on how international trade and investment agreements shape decision making.
- Regulatory chill corresponds to situations where governments choose to delay, weaken or abandon planned regulation. To apply this lens, the paper considers Better Regulation as:
  - An example of a metaregulatory instrument, that is, a "set of institutions and processes that embed regulatory review mechanisms into the everyday routines of governmental policymaking" and a sector-neutral "general mechanism of governance" (Morgan 2003).
  - A set of guiding ideas for policymaking and a toolbox (documents describing the policy process, relevant tools, procedures, and responsibilities).
  - A political determinant of health.

### Better Regulation: a political determinant of health

- The paper stresses that Better Regulation should be understood as a political tool, backing political agendas and facilitating executive control. Therefore, the paper argues that Better Regulation should be seen as a political determinant of health, shaping the context, objectives and governance logics of health policy.

- The concept of regulatory chill has its origin in international trade agreements, especially in investor-state dispute settlement mechanisms, which allow investors to challenge government policy that negatively impacts them through arbitration. Here, regulatory chill refers to delay, weakening or abandonment of regulation by governments following a perceived threat of a dispute.
- Applying this model to Better Regulation, the paper distinguishes:
  - Response chill: a reactive adjustment to regulatory scope or ambition following enforcement or a challenge related to metaregulatory norms or procedures.
  - Anticipatory chill: an adjustment because of anticipated enforcement or challenges.



### Better Regulation and pathways to regulatory chill

- The paper argues that by linking regulatory quality to adherence with a narrow set of rules and principles, Better Regulation could expose health regulation to external contestation, by actors whose interests are threatened, or internally by those seeking regulatory quality or the implementation of a political agenda.
- A first pathway for chill involves the potential for additional bureaucracy to delay the regulatory process and the introduction of new regulations (i.e., by requiring impact assessments). Evaluation and impact assessment requirements have been identified as a source of legislative delay.
- Another pathway of regulatory chill happens when commercial actors actively use Better Regulation to delay, prevent and weaken regulation, by taking part in consultation, or harnessing the norms and rules of the programme in ways that can mobilise bias.
  - Commercial actors draw on the institutions of Better Regulation discursively, to support their argumentation and support efforts to shape policy outputs (i.e., calling for more consultation and impact assessment). It also happened that rules and guidelines of Better Regulation have been invoked to challenge policy processes on the basis that they did not follow due process.
  - Furthermore, strategies have also included mirroring the Better Regulation instruments to contest their outcomes (i.e., producing alternative and competing impact assessments). This was for instance the case with the REACH regulation, regulating chemical products.

- Finally, another strategy is to target actors empowered by Better Regulation, such as the Regulatory Scrutiny Board, and present another avenue of influence.
- A third pathway of regulatory chill relates to policy makers' interpretation, understanding, and knowledge of Better Regulation. The narrative of Better Regulation pushes for regulatory quality, which can bring concerns about economic impact and regulatory burden at a higher priority level than other issues. Similarly, there is an emphasis on quantifying costs and impact, which leads to an impression that what cannot be counted is less important. Finally, by adopting the Better Regulation programme, targeting the idea that the EU creates red tape and burden, there is a risk of normalising or legitimising that very idea.
- A final pathway of regulatory chill stresses the importance of feedback loops, creating anticipatory chill. The actors of Better Regulation, by collaborating closely and regularly, tend to know the positions of each other on some issues, which can lead to some actors anticipating reactions on a proposal.
- Overall, the fact that health policy makers internalise the sources of regulatory chill is highly dependent on the policy context. Furthermore, due to the EU's settings, regulation promoting economic objectives is easier to adopt than regulation promoting social ones. The legal and political environment can therefore present a context where actors seeking to introduce ambitious change might anticipate that the proposals can suffer regulatory chill.

#### Lessons learnt

- The paper concludes that regulatory chill should be understood as a result from the use of the Better Regulation instruments in ways that are not necessarily aligned with the tools' intentions.
- The paper adds that health is a policy area where the EU mandate is limited, with weak support for integration. Initiatives rely often on entrepreneurial Commission officials. Therefore, looking at the pathways for regulatory chill illustrates how the Better Regulation agenda might result in different effects in health policy compared to other sectors. This contributes to the view, shared by civil society actors, that it has become harder to advance health protections at the EU level.