



Institutional balance rescaled? The role of soft law in shifting the balance of powers in the EU administrative space.

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RESEARCH QUESTION

- **Why** soft law instruments have entailed a shift in the balance between powers in the EU administrative space and in the relationship between EU sources as defined by that balance.

*To answer to
this question*



Interaction between soft law and other EU sources in 3 selected sectors:

- *PHARMACEUTICAL*
- *FINANCIAL REGULATION*
- *STATE AID*

How this analysis is conducted?

- **Methodology:**

1. Identification of secondary sources.
2. EUR-Lex engine - identify the connected soft law instruments by using the filter *'select all documents based on this document'*.
3. Screening by type of act and author.
4. Result - soft law documents which are founded or based on secondary sources (*see Table*).

Sector	Secondary source	Soft law
State aid	Regulation 2015/1589	Commission Notice on the recovery of unlawful and incompatible State aid.
Pharmaceuticals	Regulation 726/2004	Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006.
	Directive 2001/83	Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use.
		Guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use.
Financial regulation	Regulation 1024/2013	Guidelines on Good Distribution Practice of Medicinal Products for Human Use.
		Recommendation(s) on dividend distributions policies. Recommendation on common specifications for the exercise of some options and discretions available in Union law by national competent authorities in relation to less significant institutions.

Pharmaceuticals

- Directive 2001/83

Art. 84



The Commission shall publish guidelines on good distribution practice (GDP). To this end, it shall consult the Committee for Medicinal Products for Human Use and the Pharmaceutical Committee.



Art. 80



Holders of the distribution authorization must comply with the principles and guidelines of GDP.

Art. 47



The principles of good distribution practices for active substances shall be adopted by the Commission in the form of guidelines.



Art. 46b



Member States shall take appropriate measures to ensure that distribution on their territory of active substances, comply with GDP for active substances.

Financial regulation

Regulation 1024/2013
(Single Supervisory
Mechanism Regulation)

Art. 4(3)



For the purpose of carrying out the tasks conferred on it by this Regulation, and with the objective of ensuring high standards of supervision [...] The ECB shall adopt recommendations in accordance with the relevant binding Union law.



Recommendation(s) on dividend
distributions policies.



The ECB normally uses recommendations to harmonise the approaches taken by national supervisory authorities in relation to less significant banks (*see Recommendation on common specifications for the exercise of some options and discretions*) and also provide supervisory guidance for significant banks in specific areas (*see dividend payment policies*).

State aid

Art. 108 TFEU



Regulation 2015/1589
(‘Procedural Regulation’)



Commission Notice on
the recovery of
unlawful and
incompatible State aid.

Art. 108, second paragraph, TFEU simply enables the Commission to require the Member State concerned to abolish or alter unlawful aids —————> Art. 16 of Regulation 2015/1589 regulate the power of the Commission to issue a recovery decision —————> the Commission Notice lays down detailed rules as regards the implementation of the decision by NCAs.

Why soft law has entailed a shift in the institutional balance?



INEVITABLE SUPPLY MECHANISM OF SECONDARY LEGISLATION

Soft law provides something that hard law did not (supply), and thereby, makes its presence indispensable for the enforcement of EU law (inevitable). Under these circumstances, it impacts the way in which EU governance design is shaped, putting aside the interest to preserve the institutional balance in order to foster EU law enforcement and effectiveness.



Solutions...

Could the ECJ's judicial review restore the lost balance?

- J. Scott, *'In legal limbo: post-legislative guidance as a challenge for European administrative law'*
- L. Senden, *'Soft Post-Legislative Rulemaking: A Time for More Stringent Control'*

To answer to this
question



Analysis of the degree of the Court's scrutiny of soft law compared to hard law in pharmaceutical, financial regulation, and State aid.

Methodology:

1. In-text keyword research on the 'search form' section of the curia website.
2. Three different research: 1. Number of judgments referring to secondary sources; 2. Number of judgments referring to soft law instruments; 3. Number of judgments referring to secondary sources integrated by specific field covered by related soft law instruments.

Table 1. Number of judgments referring to secondary sources (Table 1)

Secondary source	N. of judgments
Regulation 2015/1589 (State aid)	77
Regulation 726/2004 (pharma)	55
Directive 2001/83 (pharma)	310
Regulation 1024/2013 (financial regulation)	36

Table 3. Number of judgments referring to secondary sources (Table 1) integrated by specific field covered by related soft law instrument.

Secondary source	N. of judgments
Regulation 2015/1589 (State aid)	15
Directive 2001/83 (pharma)	1

Table 2. Number of judgments - soft law instruments.

Soft law	N. of results
Commission Notice on the recovery of unlawful and incompatible State aid.	C-705/20, <i>Fossil (Gibraltar) Ltd v Commissioner of Income Tax</i>
Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006.	/
Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use.	/
Guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use.	/
Guidelines on Good Distribution Practice of Medicinal Products for Human Use.	C-7/11, <i>Caronna</i>
Recommendation on dividend distributions policies.	/
Recommendation on common specifications for the exercise of some options and discretions available in Union law by national competent authorities in relation to less significant institutions.	/

Outcomes

- The above soft law instruments rarely appear in the judgments of the Court. Exceptionally, only two judgments refer to them: 1. C-705/20, *Fossil (Gibraltar) Ltd v Commissioner of Income Tax*
2. C-7/11, *Caronna*.
- A comparison with secondary legislation-related judgments highlights how the regulations and directives are instead frequently recalled in the above case law. On the other hand, the gap is not that big in relation to judgments referring to secondary sources integrated by the specific field where soft law operates.

CONCLUSION → While the Court of Justice looks the best-placed institutional actor to rescale the imbalances caused by soft law, this analysis confirms the limited post-institutional control of the CJEU over soft law.

EX-ANTE SOLUTION

- *When secondary legislation constitutes the express legal foundation of soft law* → requirement of consulting NCAs or their representatives.
- *When an explicit delegation is not present* → extend the procedure envisaged under Regulation 182/2011 (comitology) for implementing acts.

EX-POST SOLUTION

- An approach in line with current institutional developments would be that of *recognising to/facilitating for NCAs the possibility of making a reference for a preliminary ruling.*

Thank you for the attention!