Health Economics, Policy and Law (2021), **16**, 8–22
doi:10.1017/S1744133120000043

HEALTH ECONOMICS, POLICY and LAW

ARTICLE

Reinterpreting the health in all policies obligation in Article 168 TFEU: the first step towards making enforcement a realistic prospect

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(Received 1 April 2019; revised 18 February 2020; accepted 22 March 2020; first published online 28 April 2020)

Abstract

The EU Treaties oblige the EU institutions to take health objectives and concerns into account in all policy fields. Nevertheless, this obligation is only marginally honoured in many EU policy areas at best. One problem is the lack of enforcement options to pursue further implementation. This paper examines the obligation to 'mainstream' health in Article 168 TFEU and demonstrates the difficulties in enforcing the obligation in more detail. It then offers a new, deeper interpretation of the contents of the mainstreaming obligation and discusses how this definition may be used to facilitate better enforcement in the future.

Keywords: Article 168 TFEU; enforcement; health in all policies; justiciability; mainstreaming

1. Introduction

The insertion of a public health competence into the 1992 Maastricht Treaty, and its revision in the Lisbon Treaty to what is now Article 168 TFEU, was partly a progression of the importance that health issues had been held for EU policymakers for several decades and partly a response to health crises that revealed the need for supranational health governance (Hervey and McHale, 2015). Article 168 provides that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities". This reflects the extent to which health issues have already been addressed by the EU in several areas, and the extent to which EU laws can impact the protection of health by the Member States. However, it more importantly reflects the importance of continuing to identify ways in which health concerns and EU law and policy intersect, and of committing to making policy in a way that can successfully reconcile conflicts between health interests and other policy interests, and take advantage of opportunities presented by policy agendas outside the health field to contribute to the protection of health.

This 'Health in All Policies' approach to policymaking – the recognition that a broader range of factors, other than those traditionally addressed within the 'health' field, affect population health – is not new (Ollila *et al.*, 2006; Ollila, 2011). Health in All Policies (HiAP) was first formalised on the global stage by the WHO's Alma Ata Declaration on Primary Health Care (WHO, 1978) and the Ottawa Charter for Health Promotion (WHO, 1986). It was formally adopted by the EU in 2006 at the instigation of the Finnish Presidency of the Council (Council, 2006), and is expressed in the EU Treaties through Article 168.

Although a clear catalogue of the tools available to policymakers to implement HiAP principles does not exist (Barbazza and Tello, 2014), it is possible to identify a large variety of activities that could be undertaken to effectively implement HiAP principles (WHO, 2014). Legislative

recognition and protection of health concerns in other policy fields will usually grow from the prior use of a range of policy tools – codes of practice, policy strategies and best practice guidelines – that are described as 'soft law', which Snyder defined as "rules of conduct which, in principle, have no legally binding force but which nevertheless may have practical effects" (Snyder, 1993: 32). To produce soft law, and to complement soft and hard law in the recognition and protection of health issues in other policy fields, a range of further tools are required. Examples for these are health impact assessments (HIAs), expert advisory panels, policy fora or consultation exercises. These can be described as 'new governance' in the EU context. Although new governance can only be accurately defined as ways of making policy that depart from the legislative method set out in the Treaties (Eberlein and Kerwer, 2004), it usually describes a process characterised by participation and power sharing, multi-level action, diversity and decentralisation of actors, deliberation, flexibility and experimentation (Scott and Trubek, 2002).

Despite the EU's political and legal commitment to HiAP as a policymaking strategy, the academic literature has noted that the use of HiAP tools and implementation of its principles has been intermittent, and not always effective (Koivusalo, 2010; Rosenkötter *et al.*, 2013). This not only means that EU policymaking in several areas is arguably in breach of Article 168, but more importantly that gaps are likely opening up in the protection of European citizens' health. In many policy areas inadequate implementation of Treaty obligations can be corrected through legal action against the EU institutions. However, in the health field, the ability of concerned stakeholders to hold the EU institutions to account in the courts for failure to consider the health implications of policy is notably restricted, on account of the fact that it is highly unclear what the obligation in Article 168 actually obliges the EU institutions to do or achieve.

We will argue in this paper that a more precise understanding of the obligation contained in Article 168 could improve its justiciability – its ability to be adjudicated upon in legal proceedings – which in turn may help to stimulate improved implementation of HiAP tools and principles by EU policymakers. Section 2 explains the Article 168 'obligation' in more detail, and why problems with its justiciability should be concerning. Section 3 then reviews the mechanisms through which Article 168 could in theory be enforced and explains why, in practice, judicial review of absent or ineffective HiAP implement is rarely available. Section 4 works towards closing some of these justiciability gaps by suggesting a more comprehensive definition of the HiAP obligation. It does so by building on the teleological position health is meant to have in EU policy and by using textual analysis of the legal provisions containing the HiAP obligation and scrutiny of the case law commenting on a 'high level of protection'. Section 5 then explores how combining an alternative interpretation of the justiciability of soft law with a more precise understanding of the Article 168 obligation could create opportunities for judicial review of ineffective EU engagement with HiAP tools. It will use the recent negotiation of the EU–Mercosur free trade agreement to illustrate how our arguments might apply to contemporary issues.

2. Article 168 TFEU and the 'obligation' to conduct HiAP

The phrasing in Article 168 TFEU of 'shall be ensured' is unique within the Treaties. Other complementary competences of the Union employ the wording 'shall contribute', for example in relation to education (Article 165 TFEU), culture (Article 167 TFEU), consumer protection (Article 169 TFEU) and trans-European networks (Article 170 TFEU). Indeed, in the original public health provision inserted at Maastricht, the text read "the Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States". Not only does the current framing in the Lisbon Treaty direct the EU to act directly on health issues, rather than just encourage cooperation between Member States, it also arguably raises the pursuit of HiAP to a legal obligation, as opposed to a merely desirable policy objective.

HiAP itself was never intended to be the subject of legal obligations. The Helsinki Statement on Health in All Policies affirms HiAP as a 'practical response' to the challenges facing population

health promotion and security, which provides a 'framework for regulation' and 'practical tools' for ensuring a coherent response across sectors and actors to health challenges (World Health Organization, 2013). The value of HiAP lies in "clarifying for decision-makers the links between policies and interventions, health determinants and the consequent health outcomes" (Ollila *et al.*, 2006). Thus, although HiAP is said to 'reflect' the principles of legitimacy, accountability, transparency, participation, sustainability and coordination, there is no suggestion in various declarations and supporting documents that bad implementation of HiAP should constitute grounds to argue a breach of these principles in law (Ståhl *et al.*, 2006; WHO, 2008, 2010; Leppo *et al.*, 2013). The language of obligation is deliberately absent, and with good reason – it is clear that HiAP was never designed to be 'achieved' as a policy end, but was designed as a policy tool.

Nevertheless, Article 168(1) TFEU presents HiAP as a policy end and a legally binding obligation with the phrasing 'shall be ensured'. Indeed, the reliance placed by the CJEU on Article 168 TFEU in some decisions (discussed in Section 3) supports this conclusion. Yet, it has proven very difficult to actually enforce this obligation, which includes monitoring the effectiveness of the use of HiAP tools when they are in fact being used. This is legally unsatisfactory, given that a basic component of the rule of law is that all binding obligations require mechanisms enabling their effectiveness (Poncelet, 2012). It is also democratically unsatisfactory, given that a lack of judicial oversight of soft law instruments can result in their use becoming disconnected from core constitutional values such as transparency and legitimacy (Stefan, 2014). We further argue that this situation is also normatively unsatisfactory because it undermines the idea of the EU as an organisation committed to upholding the right to health.

The inclusion of HiAP in the Treaty, as well as in Article 35 of the Charter of Fundamental Rights of the European Union (European Parliament and Council, 2012), is based on the EU's aspiration to protect the right to health. The EU has repeatedly declared that respect for fundamental rights and health equity should drive its work on health policy matters (Council, 2010: 1–4; Council, 2011: 6; Council, 2018: 2). Moreover, although the EU is not a party to the International Covenant on Economic, Social and Cultural Rights (ICESCR), which enshrines an international right to 'the enjoyment of the highest attainable standard of physical and mental health', nor the European Social Charter (ESC), which enshrines at the European level the obligation of parties 'to remove as far as possible the causes of ill-health', the EU has committed to 'intensify its efforts to promote economic, social and cultural rights', and even to 'consider accession to the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights' (Council, 2015: 11, 28).

General Comment 14 of the UN Economic and Social Council outlines that state parties to the ICESCR have an obligation to respect, protect and fulfil the right to health, and the obligation to fulfil consists of adopting "appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realisation of the right to health" (UN, 2000: 33). Although this does not apply to the EU legally, a normative conclusion can nonetheless be drawn for the EU – an organisation that claims to ground policy action in the right to health should support its rhetoric with robust legal structures that ensure the realisation of the right to health in practice. If the Article 168 obligation is not enforceable in practice, the idea that EU policy supports the realisation of health rights and health equity is normatively undermined. The next section of this paper will illustrate the difficulties in enforcing Article 168 in greater detail.

3. The justiciability of the obligation in Article 168 TFEU

Despite Article 168 placing an obligation upon the EU, it is difficult for the CJEU to declare that this obligation has been violated due to the level of generality with which the obligation is phrased. Yet, Article 168 evidently can be relied upon in court – this is clear from the fact that the CJEU have been happy to accept arguments by the EU institutions that Article 168

supports EU legislation that has the objective of promoting health. For example, the Tobacco Products Directive (European Parliament and Council, 2014a) was challenged in *Philip Morris* on grounds that certain provisions constituted a disproportionate restriction on the economic freedoms of tobacco producers. The CJEU held that the EU legislature had proportionately balanced the economic consequences of the Directive with "the *requirement* to ensure, in accordance with…[Article] 168(1) TFEU, a high level of human health protection" (C-547/14: 190, emphasis added). Directive 2006/134 on the composition of plant protection products was challenged in *Gowan Comércio Internacional* on grounds that certain of its prohibitions was unsupported by scientific studies. The CJEU upheld the validity of the Directive and stated that "as provided in Article 168 TFEU, requirements relating to the protection of human health are a part of all the policies and actions of the Union and *must* therefore be taken into account in the implementation of the common agricultural policy" (C-77/09: 71, emphasis added). Therefore, the CJEU clearly accepts that Article 168 places a legal obligation upon the EU that can be relied upon in court.

However, the limited case law indicates that the CJEU is unresponsive to arguments that the EU institutions have breached the obligation in Article 168 by acting in ways that do not appear to ensure a high level of health protection. For example, in *TestBioTech*, the applicants asked the General Court to annul a decision of the Commission to endorse the European Food Safety Authority's approval of a new type of genetically modified soybean, on grounds that the health implications of the decision had not been sufficiently considered. Although the General Court did accept that the EU institutions are bound by Article 168, it was unwilling to commit to any objective benchmark below which the level of health protection secured by an EU act is inadequate. Instead, they held that "it is for the Commission to make use of its broad discretion to identify what it considers relevant to its risk assessment" (T-177/13: 106–109). In *Spain vs Commission*, Spain sought the annulment of Commission Regulation 15/2011 on grounds that the changes it made to approved methods for detecting marine bio-toxins in food generated risks to public health. The General Court held that the Commission had not committed a manifest error of assessment in approving a switch in testing methods, and repeatedly asserted that Spain had not sufficiently demonstrated that the evidence proved that the alleged risk to public health was a breach of the Article 168 obligation – a difficult task if there is no clear or specific standard of proof that must be reached. Even if a decision by EU policymakers is not fully supported by evidence, the obligation to secure a high level of health protection will not necessarily be breached (T-204/11: 112). It therefore appears to be much harder to convince the CJEU that a particular policy or decision is *illegitimate* based on the obligations contained in Article 168, than it is to convince them that it is legitimate. This can be attributed to the fact that 'a high level of human health protection' is too vague a standard without further clarification. Certainly in light of the wide margin of discretion given to the EU institutions in health policy (C-547/14: 166), it appears that 'a high level of human health protection' may be interpreted to accommodate a wide range of action and inaction.

Even if an applicant has a good evidential case that EU action is insufficient to discharge the obligation in Article 168, poor implementation of HiAP principles still might not be judicially reviewable. Article 263 TFEU enables the CJEU to review the legality of EU acts, and Article 265 enables the CJEU to review failures of the EU institutions to act. However, acts or failures to act must be admissible, and many tools of HiAP would not meet this admissibility threshold due to their soft law or new governance status.

The Treaty and case law are clear that an action under Article 265 will only succeed if the Commission had completely failed to define a position on a specific action that was requested of it (C-637/15 P; T-382/11). For example, a refusal to conduct an HIA for a particular policy constitutes a definition of a position. Thus, in any instance where the Commission has considered but ultimately decided against the use of a HiAP tool, an action under Article 265 would be inadmissible. Moreover, ineffective or inappropriate implementation of HiAP tools cannot be

reviewed under Article 265, since the CJEU made clear in *Bukl* that this action is only available to sanction "failure to take a decision or to define a position, not the adoption of a measure different from that desired or considered necessary by the persons concerned" (C-15/91: 17).

If the Commission had genuinely not defined its position on the use of a particular HiAP tool, according to Article 265, an action "shall be admissible only if the institution, body, office or agency concerned has first been called upon to act". The request for action must be clear enough to allow the Court to adjudicate on whether there has been a failure to act, and it must be made within what is effectively a 4 month limitation period. General calls to act in line with HiAP principles, such as the invitations often made by the Council to the Commission in various Council Conclusions on health topics, are likely not specific enough to meet the high threshold demanded for a successful Article 265 action (Council, 2006, 2010, 2017*a*, 2017*b*).

The conditions for judicial review under Article 263 TFEU are also strict. The action for annulment under Article 263 allows the CJEU to strike down EU acts that constitute an infringement of the Treaties or any rule of law relating to their application. However, only an act that is intended to produce binding legal effects can be reviewed under Article 263, and on the case of refusals to adopt an act, the act that would have been adopted must have been intended to produce binding legal effects (C-43/65). As will be explored further in Section 5, the meaning of 'binding legal effect' can also include certain legal effects that are generated indirectly by the practical impact of soft law and new governance mechanisms, and this potentially offers a pathway to the reviewability of certain HiAP tools. However, the paradigmatic understanding of soft law means that the default position for the CJEU would be to find that refusals to adopt soft law or engage with new governance mechanisms, or inadequate engagement with these tools, are not admissible under Article 263 (AG Bobek, C-16/16 P: 118). Even if the Commission was to refuse to adopt proposals for harmonising measures that would systematise conditions governing health issues (de La Rosa, 2012) – as they have done repeatedly for example on alcohol policy (Bartlett and Garde, 2017) – proposals and strategies are preparatory acts, and are not reviewable (C-31/13 P: 55).

The problems with the justiciability of Article 168 and of the tools that must be used to discharge the obligation are compounded by the fact that Member States have closely, if not altogether successfully, defended their primacy in health policy (Vollaard and Sindbjerg Martinsen, 2017). This means that few states are likely to actively seek opportunities to hold the EU institutions to account for ineffective implementation of the Article 168 obligation, as this may draw attention to the debate on deeper integration of health policy. This is an unfortunate irony given that one of the supposed benefits of soft law and new governance mechanisms is to facilitate supranational collaboration and action within sensitive policy areas.

4. A more nuanced understanding of the obligation in Article 168 TFEU

In light of the difficulties in the justiciability of the EU's HiAP obligations, we propose an alternative, clearer understanding of Article 168, which may help to resolve some of the issues identified in the previous section.

The HiAP obligation has three main elements defining 'what' it actually is that must be ensured in all policies. Although 'health' as a concept is difficult to define conclusively (Huber *et al.*, 2011), the European Social Charter (ESC) reaffirms the WHO definition of health being "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (Council of Europe, 2015: 240, 295), and whereas the European Union is not a party to the ESC, the CFREU and the official explanations accompanying it ((European Parliament, Council of the European Union and European Commission, 2007) make wide reference to the ESC and provide the link between this definition of health and EU law.

Several variations of 'health' are mentioned throughout EU law, such as animal or plant health (Article 36 TFEU), or the health of specific groups of humans, such as workers (Article 45(3)

TFEU) or consumers (Article 169(1) TFEU). Nevertheless, there is currently no debate surrounding a further definition of 'human health'.

In cases of doubt, generally a wide understanding of 'health' should be adopted in line with the relevance health has been attributed in EU law. In any case, the precise definition of 'health' is unlikely to be challenged or to be the one to cause uncertainties *vis-à-vis* the enforcement of HiAP. A similarly straightforward definition applies with regards to the HiAP element of 'protection'. More precisely, the relevant question regarding this element is whether the HiAP obligation should be understood to entail a broad definition of the term 'protection'. In this case, the mainstreaming of health in all policies would also encompass promoting measures.

A strictly textual analysis of the term high level of human health 'protection' might lead to the exclusion of many policy areas and actions from the obligation. Protection, as opposed to promotion, is the defensive shielding from a negative influence or damage, rather than accepting and embracing supportive behaviour (Merriam-Webster Online, 2018). If one were to follow this narrow literal interpretation, the scope of the mainstreaming obligation left in this context would be measures aimed at reducing or mitigating harmful effects on human health. However, there would be no obligation for policies to accommodate approaches which seek to enhance human health.

Ultimately, the narrow interpretation focussing on literal protection only is unconvincing. It contradicts the important position health has been given in EU law. Furthermore, the understanding of 'promotional' activities as part of a high level of human health protection has been affirmed, albeit not discussed in detail, by the Council on multiple occasions (Council, 1995) and in the literature (Van Der Mei and Waddington, 1998: 135; Hervey and McHale, 2004: 77).

The element most difficult to define and most decisive for the effective enforcement of the HiAP obligation is the question of what constitutes a 'high level' of human health protection pursuant to Article 168(1) TFEU. The definition of what constitutes a 'high level' of protection dictates what the different policy areas absolutely have to ensure in order to comply with the HiAP obligation.

Two issues must be reconciled in order to reach a definition of a 'high level' of protection – the narrow interpretation EU case law seems to indicate and the teleology, namely the relevance health has been attributed in EU law overall, as highlighted above.

This issue has only been marginally discussed in the literature and jurisprudence so far. Although the wording 'a high level' can be found in a number of Treaty provisions and in relation to a variety of mainstreaming aims (e.g. security in Article 67(3) TFEU; employment in Article 147(1)), the two areas demanding a 'high level of protection' are health and the environment. For the purposes of this discussion, it is important to highlight that the literature debating this issue currently only consists of contributions by de Sadeleer (2006, 2010, 2013) and Misonne (2015), who discuss the issue primarily with a view to EU environmental policy. However, given the nearly identical wording of health and environmental protection norms in EU law, both calling for a 'high level of protection' (Articles 168 and 191 TFEU), the discussion is still relevant to the definition of a high level in the context of human health protection. In addition to the wording, it is important to acknowledge that there are broad overlaps between environmental protection and health protection and the fact that the former significantly affects the latter, further underlining the appropriateness of drawing analogies.

Although the courts do not define these elements of the health mainstreaming obligation in a way which could facilitate consistency throughout and between EU policies, there are several decisions which are helpful in inferring a frame of what constitutes a 'high level' of human health protection.

As pointed out, there is no ultimate definition of a 'high level' of human health protection. Providing a final, singular definition is neither possible nor desirable. After all, the rationale behind HiAP is that many different policies and variables can have varying different effects on health. The appropriate 'high level of human health protection' must be determined on a case-

by-case basis. Nevertheless, more clarity is an integral requirement for more effective enforcement of the HiAP obligation.

In light of this, this approach suggests understanding a 'high level' of protection as a spectrum with more closely defined 'upper' and 'lower' benchmarks between which the obligation of a 'high level of human health protection' can be considered as fulfilled.

The maximum level of required protection arising from an obligation towards a high level of protection is easy to address, as this point has been discussed in case law. In cases like *Safety Hi-Tech* (C-284/95: 49) or *Bettati* (C-341/95: 47), which concern a high level of protection of the environment, the Court explicitly pointed out that "whilst it is undisputed that Article [191(2) TFEU] requires Community policy in environmental matters to aim for a high level of protection, such a level of protection, to be compatible with that provision, does not necessarily have to be the highest that is technically possible" (C-284/95: 49).

The *Alpharma* case (T-70/99) concerned a dispute regarding additives in animal feed and their effect on human and animal health. In this case, the Court picked up the wording of and explicitly referred to *Safety Hi-Tech* in its elaboration on the obligation to ensure a high level of human health protection based on Article 168(1) TFEU (then Article 129(1)). It concluded that in order to comply with the HiAP obligation arising from Article 168 TFEU, policies do not necessarily have to afford the highest level of protection possible (T-70/99: 165). This confirms the understanding of the 'upper benchmark' of a high level and, more importantly, demonstrates its applicability to mainstreaming explicitly in a health context.

In order to still sufficiently fulfil the obligation to pursue a high level of health protection, EU policies may, thus, stay short of the highest possible level they could achieve. Although this upper benchmark still cannot be considered conclusive, it is important for clarifying that there is some leeway for other policy objectives to prevail, even if touching on health issues. Ultimately, it is unlikely that a situation would arise in practice in which non-health policy areas seek to go beyond the necessary requirement of a high level of public health protection to an unacceptable detriment of their own policy objectives.

The much more relevant question with regards to effective implementation and, lacking that, the necessary enforcement of the HiAP obligation is what constitutes the 'lower end' of the high-level frame, i.e. the lowest level of human health protection which can still be considered as sufficiently high to fulfil the HiAP obligation.

In cases like *Affish* (C-183/95: 43), *Pfizer* (T-13/99: 456) or *Químicas* (T-158/03: 134), the courts explicitly pointed out that the pursuit of human health protection "may justify adverse economic consequences, even those which are substantial, for certain traders. The protection of public health 'must take precedence over economic considerations". In justifying this stance, they either draw closely on the usual wording "high level of protection of the health of humans" (C-183/95: 43) or even refer explicitly to the relevant Treaty provisions for health (T-13/99: 114, 456–457).

The Court's stance attributes perspective to the cases dealing with the highest necessary level of protection and underlines that, even if pursuing the highest possible level of health protection is not necessary to fulfil the obligation, economic objectives may have to step back in favour of public health objectives in order to fulfil the obligation. This demonstrates that in order to ensure the 'lowest acceptable' level of health protection in the context of the HiAP obligation, there is still significant emphasis on health. In light of these cases, it is unlikely that any policy or measure which entirely disregards health protection in favour of economic objectives or entirely ignores the HiAP toolbox could withstand scrutiny.

This conclusion, however, still does not provide the necessary clarity to determine a workable minimum-necessary level of human health protection. The necessity of flexibly considering the HiAP obligation in its individual context on a case-by-case basis must be acknowledged again. However, guidance to anticipate the classification of a measure or policy as sufficiently high

can be drawn from the case law, albeit not offering a definition as binding and explicit as might be desirable from a legal certainty point of view.

An indication towards the minimum necessary level of health protection can be found in the case law mentioned above, which deals with environmental protection. Analysing these cases, de Sadeleer sees the EU institutions as "not only required to avoid degradation of the environment, but [that they] must also seek to improve its quality as well as their citizens' standard of living" (de Sadeleer, 2013: 450). According to de Sadeleer, an important step in achieving a high level of protection is to pursue a 'policy of prevention' (de Sadaleer, 2013: 455; see also Misonne, 2015: 11, 12, 26). This approach also underlines this paper's findings regarding the meaning of 'protection'.

de Sadeleer refers to the Advocate General Opinion in *Bettati*, in which Advocate General Léger interprets the obligation towards a high level of protection to mean that the EU legislator is under an obligation to constantly 'improve' policies already pursued (AG Léger, C-341/95: 67; de Sadeleer, 2013: 459).

Misonne, on the other hand, takes a somewhat narrower approach to defining a high level of protection. She endorses a 'principle of no-regression' (Misonne 2015: 22). This principle was established in relation to *France vs Commission* (T-257/07) and Regulation 999/2001 (European Parliament and Council, 2001), which dealt with the regulation of 'Mad Cow Disease'. Article 24a of the Regulation, inserted by Regulation 1923/2006 (European Parliament and Council, 2006), states that decisions "shall be based on an appropriate assessment of the possible risks for human and animal health and shall, taking into account existing scientific evidence, maintain, or if scientifically justified increase, the level of protection of human and animal health ensured in the Community". In *France vs Commission*, the General Court affirmed in passing an obligation to *maintain* a high level of protection of human health based on Article 24a of Regulation 999/2001. More importantly, the General Court explicitly links this obligation further to Article 168(1) (Case T-257/07: 249, 266), clearly extending the applicability of this benchmark beyond the scope of Regulation 999/2001 and to all cases with health implications. In the appeal case, the Court also re-affirms the idea that the level of health must not be lowered from the current one (C-601/11 P: 134).

The 'no-regression' rationale is also reflected with regards to fundamental rights. Article 53 CFREU states that "[n]othing in this Charter shall be interpreted as restricting or adversely affecting human rights". The Explanatory Note on this provision further clarifies that "[t]his provision is intended to *maintain* the level of protection currently afforded within their respective scope by Union Law, national law and international law" (emphasis added).

Against the background of these two approaches to a 'high level' of protection, two final issues must be reconciled. On the one hand, the main finding of this subsection is that, according to the courts, the current level of health protection chosen by the EU must be maintained in order to fulfil the mainstreaming obligation. On the other hand, this approach is, arguably, rather cautious in light of the position 'health' has been attributed throughout the Treaties overall. The maintenance-approach also does not stem immediately from the courts' interpretation, but was rather introduced by the wording of Article 24a of Regulation 999/2001 and merely accepted by the courts. Ultimately, the question of what constitutes a 'high level' of protection was not a deciding factor in *France vs Commission*, and the courts therefore had no incentive to engage more deeply with the concept and the teleology underpinning it.

This paper therefore proposes a 'split approach' to understanding the obligation of what constitutes a 'high level' of human health protection. This addresses the need for effective enforceability and legal certainty, but also somewhat moves past the cautious approach of the courts and puts a stronger focus on the normative aspect of the mainstreaming obligation and the relevance of health throughout primary law. Of course, the level of health protection should be adapted to the most recent scientific evidence with regards to the precautionary principle. However, it is proposed to go further than that under certain circumstances.

Under the approach proposed here, a distinction should be drawn between policy implementation and policymaking. Differentiating between separate 'stages' in the policy-process has been discussed in the literature (Wallace, 2000: 73; Franklin, 2011: 56; Hill and Hupe, 2014: 5). It should be considered 'policy implementation' when the EU makes individual, executive decisions (Mazmanian and Sabatier, 1983: 20–21). 'Policymaking', on the other hand, should be understood as the stage proposing and defining the content of a policy (Wallace, 2000: 73). Granted, the distinction is not an absolute one and it has been noted that it is not always clear where to draw a definitive line between the stages (Wallace, 2000: 73). This becomes clear e.g. when considering that in passing EU legislation, concrete norms certainly serve to 'implement' the EU's broader policies. However, for the purposes of the HiAP obligation, legislation should be viewed as part of the policy-making stage, as it does not have an individual and executive nature and function as such.

When implementing policy, e.g. when making decisions on competition law or funding, the current level of health protection should be the decisive benchmark. This approach provides more legal certainty and enhances consistency between decisions in different policy areas.

At the policy-making stage it should always be the aim to improve the current level of human health protection. This improvement should, of course, be influenced by scientific evidence, if available. However, it should not depend on whether there is new scientific evidence to inspire a positive impact on the level of health protection in policymaking. Instead, the mainstreaming obligation should be understood as always requiring an improvement of the current level of human health protection in policymaking, if at all possible. This approach maintains legal certainty for stakeholders. At the policy-making stage, individual stakeholders are not yet addressees of decisions or measures and are therefore not affected, even if the precise increase in the level of protection adopted in the new policy cannot be predicted from the outside.

This understanding not only reconciles case law and teleology, it also represents a compromise between the existing views on this matter. It is more cautious than the approach endorsed by de Sadeleer, who seems to support an increase in the level of protection under all circumstances, whereas going beyond the Court's findings in *France vs Commission* and Misonne's approach. The split approach can be considered to be in line with the strict wording of AG Léger's Opinion in *Bettati*, which referred to the '*législateur communautaire*' (AG Léger, C-341/95: 77).

5. Applying the split approach to the Article 168 obligation to improve its justiciability

In this final section, we will argue that if tools of HiAP were to be justiciable under Article 263 TFEU, adopting our split approach to the Article 168 obligation would considerably increase the likelihood of the CJEU being able to find a breach of it, by providing an objective benchmark against which the CJEU can assess the impact of, for example, the failure to conduct a HIA where it might have been useful. We will first consider in more depth the possibilities for soft law and new governance mechanisms to be justiciable, then we will illustrate how these possibilities, when combined with our split approach, might improve the justiciability of Article 168.

Conducting a HIA for directives or regulations that may have an impact upon the protection or promotion of health is an example of how HiAP tools should be used to successfully discharge the Article 168 obligation to promote a high level of health in all EU policies. It could broadly be classified as an example of a new governance mechanism. The Commission's Guidelines on Impact Assessment (IA), a soft law instrument, recommend that a HIA is necessary for every piece of legislation with potentially important health implications. However, as we showed above, it is very difficult to demonstrate that the deliberate or non-deliberate omission of a HIA by the Commission when putting forward proposals for new legislation in fields outside of health is a breach of Article 168. This is because there is no clear benchmark to the Article 168 obligation against which the CJEU could judge the effects of failing to conduct an HIA,

in addition to the fact that neither the recommendation to conduct an HIA nor the proposal under scrutiny would normally be considered justiciable under Article 263 TFEU.

It may, however, be possible in certain circumstances to argue that the decision not to use HiAP tools, or the misuse of these tools, creates sufficient legal effects to allow that decision to be reviewed under Article 263. Stefan and others have argued that soft law can be justiciable when its use creates certain expectations, the fulfilment of which is protected by general principles of EU law (Stefan, 2012, 2014; Kovács *et al.*, 2016). As Stefan points out, the publication of soft law may create certain expectations for the way in which EU institutions will act. If the expected action does not materialise, the institution may breach general principles of EU law such as the principle of legitimate expectations or the principle of legal certainty. This may especially be the case where the publication of soft law is intended to clarify or add to obligations already established in hard law (Stefan, 2014).

To this, one might also add the general principle of fundamental rights protection (C-11/70), as codified by the CFREU. Very few cases have come before the CJEU on the interpretation of Article 52(5) of the Charter, which addresses the circumstances in which the social principles of the Charter are justiciable. The Advocate General's suggested interpretation of Article 52(5) in *Association de médiation sociale* (AG Cruz-Villalón, C-176/12) would exclude the possibility of the compatibility of soft law instruments with the right to health being reviewable, but that reasoning seems to have been rejected, or at least ignored, by the Court. In the later case of *Kotnik* (C-526/14) the national court asked whether certain provisions of a Commission Communication, a soft law instrument, were precluded by the right to property. Both the Advocate General and the Court noted that the Communication was not binding but nevertheless, in light of the legal effects that the Communication could produce, examined the compatibility of the contested provisions with the right to property at great length. Although the eventual conclusion was that they were compatible, this case illustrates that the Court may be willing to consider an argument that ineffective use of HiAP tools is incompatible with the right to health, if sufficient evidence of legal effects can be provided.

Although the approach of the courts towards the justiciability of soft law instruments might sometimes appear static, it is clear that this approach can evolve over time. This can be observed in the way in which the CJEU has treated the soft law surrounding the Framework Convention on Tobacco Control (FCTC). The CJEU has begun to rely upon the status and content of Guidelines drawn up by the Conference of the Parties to the FCTC to justify rulings which uphold the legality of Member State and EU tobacco control legislation (C-547/14; C-358/14). This contrasts with previous tobacco jurisprudence in which both the Court and its Advocate General insisted that the content of Recommendation 2003/54 on initiatives to improve tobacco control could not support an argument for the legality of certain strong tobacco control measures (C-221/08). Several years later, the Court and its Advocate General appear to accept that the FCTC guidelines can, and indeed are intended to be relied upon in exactly this way.

If soft law relevant to HIAs were found to be justiciable by the CJEU through the legal effects created, our split approach to the Article 168 obligation would increase the likelihood that the CJEU could find a breach of the obligation. Under the split approach, action to implement existing policy should not objectively lower the protection of human health compared to the level of protection that is currently offered, and action to amend or create new policy should provide objectively greater protection compared to that provided for previously. This differs to the CJEU's current approach to Article 168, which does not employ any explicit benchmarks against which the level of health protection offered by a policy is assessed.

The negotiation of the EU–Mercosur free trade agreement provides a suitable case study for the application of our arguments. On 28th June 2019 the EU and Mercosur (the trading bloc comprising Argentina, Brazil, Paraguay and Uruguay) reached political agreement on the content of a free trade agreement. The draft agreement has been criticised by public health NGOs, who have identified a number of impacts that the agreement could potentially have

upon health protection (Health Policy Watch, 2018; EPHA, 2019). In addition, a number of health scandals in Mercosur countries were reported on during the course of recent negotiations, including negligence and corruption in the inspection of Brazilian meat packing factories that had been putting unsanitary meat products into the export market (New York Times Online, 2017).

Against this background, it was only on 3rd October 2019 that the interim report for the Sustainability Impact Assessment (SIA) commissioned on the Mercosur agreement was published (LSE, 2019). The delay in preparing and releasing the report has been criticised by health NGOs (EPHA, 2019), not least because the only IA that had previously been conducted on the deal, in 2011, made no mention of potential health impacts at all (European Commission, 2011).

The Better Regulation Guidelines on IA published by the Commission specifically state that "all potential impacts (positive or negative) should be mapped out according to their expected magnitude and likelihood and to the specific parties that would be affected", and that these should include 'impacts on health' (European Commission, 2017: 25). These Guidelines were adopted specifically to support the effective implementation of the Interinstitutional Agreement on Better Law-Making, which provides that IAs should "be presented in such a way as to facilitate the consideration by the European Parliament and the Council of the choices made by the Commission", and that "any additional impact assessment work conducted during the legislative process by the Institutions will be made public by the end of the legislative process" (European Parliament and Council, 2016: 12, 14, 18).

With respect to the assessment of the health impacts of the proposed Mercosur agreement, an argument could be made that the timing of the release of the interim SIA does not fulfil the expectations generated by the Guidelines on Impact Assessment and Interinstitutional Agreement, with regards to the obligation in Article 168. An expectation arguably exists that during the process of negotiating a free trade agreement of the scale and importance as the Mercosur agreement, pressing and relevant health impacts for EU citizens will be identified in a timely manner, so that trade policies that promote the health of EU citizens can be pursued. Publishing the interim SIA on 3rd October 2019 cannot be considered to meet these expectations. Several potential negative health impacts for EU citizens are highlighted by the interim SIA, including increased sugar and alcohol consumption, and compromises to food safety (LSE, 2019: 138, 152, 163). Yet a political agreement between the EU and Mercosur had already been reached on 28th June 2019, meaning that the other EU institutions and the Member States were not able to properly consider the implications of the SIA's analysis of these negative health impacts before the negotiations were brought to a meaningful conclusion.

The recent Opinion of AG Sharpston in *Czech Republic vs Parliament and Council* indicates that, although the completion of an IA is not a legal condition for enacting legislation, IAs are expected where significant impacts are likely, and that the absence of an IA in such circumstances may breach general principles of EU law (in this case the principle of proportionality) if justification is not provided (C-482/17: 99). Following this line of reasoning, the Commission has not provided justification for why the SIA was not published in time for its analysis on significant health impacts to inform the negotiations. This failing could be enough to constitute a breach of the expectation that a timely HIA would be provided so as to facilitate consideration of how the Mercosur agreement could be negotiated in a way that met the Article 168 obligation to ensure a high level of health protection. This argument would require one to show that the failure to meet the expectation has led to EU citizens receiving a less-than-high level of health protection, which our split approach may facilitate.

It is possible that the failure to present the SIA results in time will have led to the level of health protection afforded to European citizens being compromised in significant ways, if the agreement as it currently stands is taken forward to a binding legal text. Without a particular benchmark for the Article 168 obligation, it would be difficult to pinpoint the level of health protection that EU citizens should legally receive under this trade agreement, and thus difficult to hold the

Commission to account for any compromises to health protection that occur because an HIA was not available in sufficient time to inform debate on those health issues. Under the split approach to Article 168, any new policymaking that will not objectively advance health protection, whatever the particular starting point, will be contrary to the Article 168 obligation. This is a much clearer benchmark to assess the consequences of a delayed HIA against. If specific potential negative health impacts of the Mercosur agreement were not brought to light in sufficient time to inform the negotiations, they may not have been addressed, and in such circumstances it is unlikely that an increased level of health protection for EU citizens will have been ensured.

The following provides a small illustration. The SIA specifically notes that foot and mouth disease (FMD) is a "major concern for Mercosur exporters", that "there is not a single FMD status across Mercosur", and that there are "not only variations between countries but also within the different regions" (LSE, 2019: 111). The SIA then notes that "[d]espite the variations, Mercosur countries have made enormous efforts to improve their sanitary status and they continue work to improve it. The status is not an impediment to export to the EU" (LSE, 2019: 111). However, given the evidence presented on the variability in each country's control over FMD, this assurance does not appear convincing, and the SIA's data arguably justify much closer consideration of how the sanitary and phytosanitary (SPS) regulatory regime should apply to exports of beef from Mercosur states. Yet, these data were not available for wider scrutiny during the negotiations, and the politically agreed text of the SPS Chapter articulates the general principle in Article 6 (2) that "[t]he SPS requirements of the importing Party shall be the same for the entire territory of the exporting Party, as long as the same sanitary and phytosanitary conditions prevail", with a complex procedure detailed later in the Chapter for recognising regional exceptions to this principle when conditions are not the same. The current text of the agreement arguably does nothing in particular to improve the protection of EU citizens against the risk of unsanitary beef exports from Mercosur states, and had the SIA data been available for scrutiny earlier, additional protocols could conceivably have been negotiated for a tailored SPS regulatory regime to apply to trade in beef, in the same way that such a protocol was negotiated to apply to trade in motor vehicles.

If the HiAP tools employed in this scenario were justiciable in the manner suggested above, and given the clearer and more specific benchmark proposed by the split approach to Article 168, it may be possible for the CJEU to find that the Commission has breached legitimate expectations connected to the health mainstreaming obligation. It failed to provide a timely IA of the potential health impacts of the Mercosur agreement, as was expected in accordance with the Commission's own Guidelines on IA, which could objectively have led to EU citizens receiving less than improved health protection under certain parts of the agreement. Given the number of interests that this agreement impacts upon, it is conceivable that there may be parties willing to put this argument before the CJEU, in order to prevent the negotiations from proceeding further without due consideration being given to health protection. For example, the Irish government has already voiced its opposition to the agreement, due to the threat of the agreement dramatically reducing the competitiveness of Irish beef farmers, with possibly existential consequences. A Member State in this position might consider a legal challenge to the agreement if they felt that it would likely be ratified despite their objections.

6. Conclusion

This paper sought to demonstrate how a clearer understanding of the EU's obligations under Article 168 TFEU, and the pathways for enforcement of this obligation, could increase the impact of HiAP commitments made in EU primary law. It has proposed a new split approach to the obligation to ensure a high level of health protection, focussing particularly on what a 'high level' should mean. It then illustrated how HiAP tools might be justiciable under Article 263, and how the split approach would help the CJEU to identify a breach of the Article 168 obligation if these HiAP tools had not been used effectively to protect the health of EU citizens.

We recognise of course that relying on the text of the Treaty alone will not be enough to ensure that HiAP principles are actually employed effectively. Other aspects of successful HiAP implementation, besides the wording of EU primary law, must be subjected to more thorough critical scrutiny. These include the ownership of political responsibility for HiAP implementation, and the methods by which HiAP is deployed by EU policymakers. We call for further research into these questions. A functioning enforcement mechanism for HiAP in the EU would be a welcome first step, but must be complemented by a better understanding of the true level of practical work involved in successfully implementing HiAP principles.

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Cite this article: Bartlett O, Naumann A (2021). Reinterpreting the health in all policies obligation in Article 168 TFEU: the first step towards making enforcement a realistic prospect. *Health Economics, Policy and Law* **16**, 8–22. https://doi.org/10.1017/S1744133120000043