A Battle of the Norms in EU Chemicals Regulation Space: Reflections on the Court of Justice Decision on the Concept of "Articles" Under REACH

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Judgment of the Court (Third Chamber) delivered on 10 September 2015 in Case C-106/14, Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'écologie, du développement durable et de l'énergie.

I. Introduction

The regulation of chemicals in the EU is diffuse, there being more than 150 separate pieces of legislation that concern, in some fashion, the control and use of chemicals.[1] Since 2007, the primary piece of control legislation is REACH, the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals.[2] At its most basic, REACH requires the generation of data on the intrinsic properties of certain chemical substances (around 45,000 of the 105,000 substances currently on the market) by the private sector (namely, the manufacturers, importers and, in limited circumstances, downstream users of those chemical substances) followed by the registration of those substances (accompanied by their testing data) with the European Chemicals Agency (ECHA).[3] Certain substances identified as particularly harmful to human health or the environment will be banned (either in full or in certain applications);[4] others may be granted a time limited authorisation by the Commission to remain on the market if it can be proved that the associated risks can be adequately managed, or where the use can be justified on socio-economic grounds and no suitable alternatives are available.[5]

REACH has been called, 'possibly the most controversial and complex piece of legislation in European history'.[6] It is vast: the text of the Regulation alone stands at more than 130,000 words with guidance produced by ECHA amounting to more than one million words.[7] An issue with one of ECHA's guidance documents lies at the heart of this paper. In April 2014, the Court of Justice of the European Union was asked to rule on the proper interprepation of one aspect of REACH. This concerned the meaning of the term "article". Advocate General Kokott gave her Opinion on 12 February 2015. The Court ruled on 10 September 2015. The following is broken down into four parts. It begins by setting out the relevant provisions in REACH, and how those provisions were framed in guidance produced by ECHA. The review then turns to the facts of the case before setting out the ruling of the Court. It finishes by discussing the normative tensions between 'guidance' promulgated by EU agencies.

II. The REACH Obligations

Article 33(2) of REACH grants to consumers a limited 'right to know' about the products they buy and the substances contained therein:

> "On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) [i.e. substances on the Candidate List] in a concentration above 0.1 % weight by weight (w/w) shall provide the consumer with sufficient

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1 Commission, Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH: Staff Working Document SWD (2013) 25 final, 4.

2 European Parliament and Council Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L33/1 (hereafter 'REACH').

3 REACH, Article 6.

4 REACH, Title VIII.

5 REACH, Title VII.

6 Gunter Verheugen, EU Industry Commissioner. See: <http://www.telegraph.co.uk/news/worldnews/europe/1503325/Most-controversial-European-law-wins-parliamentary-approval.html#>

7 See: <guidance.echa.europa.eu/ guidance.echa.europa.eu/>

> information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance."

The relevant information has to be provided, free of charge, within 45 days of the request. The term "consumer" is not defined in REACH, but a "supplier of the article" means "any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market".[8] The definition of what constitutes an "article" is equally broad and is the subject of the present case. Under Article 3(3) "article" means "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition". Article 33(1) is a form of mirror to Article 33(2), but applies to non-consumers ("recipients of articles")[9] and is a positive, pro-active obligation to provide information on the "safe use" of applicable "articles" (rather than the reactive Article 33(2) which requires the trigger of a request for information from the consumer).

In addition to the 'right to know' provisions detailed above, there are also notification obligations on suppliers to notify ECHA, under Article 7(2) of REACH, if certain conditions are met regarding the content of Candidate List substances of very high concern in "articles" they supply. Notification is required when: (a) the substance is present in those "articles" in quantities totaling over one tonne per producer or importer per year; and (b) the substance is present in those "articles" above a concentration of 0.1 % weight by weight (w/w). Notification is only required where the substance has not yet been registered for that specific use.[10]

Accompanying the Article 7 and Article 33 obligations in REACH are further directions in ECHA Guidance, a Commission 'Note' and a piece of French law. The Court in the present case refers to each of these. The April 2011 'Guidance on Requirements for Substances in Articles' produced by ECHA makes it clear that the Article 7(2) threshold concentration applies to articles as produced or imported and "does not relate to the homogeneous materials or parts of an article, as it may in some other legislation".[11] ECHA gives the following example in their Guidance:

> "If imported buttons for jackets contain such substance in concentrations of 0.5% (w/w), this needs to be communicated to the recipient. If these buttons are imported as part of jackets the concentration of the substance in relation to the imported article (the jacket) will probably be lower than 0.1% (w/w) and in that case no information would have to be communicated."[12]

This is an important exposition on the meaning of an "article", which has important real world consequences. As Bergkamp and Herbatschek note, some "articles" (aircraft, cars, toys and machinery, among others) may be made up of hundreds or even thousands of individual components.[13]

ECHA has produced over 20 Guidance documents, more than 1,000,000 words to accompany REACH. However, the 'Guidance on Requirements for Substances in Articles' is the *only* ECHA guidance document to come with a front-page warning that it "did not find full support by consulted national authorities." The story of this warning is illuminating. A Swedish NGO performed a study on plastic shoes, which showed that they contained phthalates (DEHP and DBP) in very different concentrations, depending on which method of calculation one used.[14] Once this study was published, different Member States took sides on which method of calculation was more appropriate: the calculation which saw the finished shoe as a single object; or the calculation which looked at the various components that comprised the shoe (which has come to be known as the "once an article, always an article" approach). Unable to come to agreement on which approach was most suitable, ECHA published guidance that was accepted by the majority, but not all, of the national authorities of the EU/EEA Member States. The European Commission was of the same view as ECHA and the majority Member States. A 'Note' it published on of 4 February 2011 sets out that, "The Commission has come to the conclusion" that the Article 7(2) and 33 obligations ap-

8 Article 3(33)

9 Article 3(35) defines a recipient of an articles as "an industrial or professional user, or a distributor, being supplied with an article but does not include consumers"

10 Article 7(6)

11 ECHA, *Guidance on Requirements for Substances in Articles* (Version 2, April 2011) para 2.2. See: http://echa.europa.eu/documents/10162/13632/articles_en.pdf

12 ECHA, ibid, para 2.3

13 L. Bergkamp and N. Herbatschek, 'The "Once an Article, Always an Article" Approach" (2015) 1 EJRR 155

14 For a more detailed review, see: Marianne Hoppenbrouwers, 'The Story of the Button on the Jacket – Substances in Complex Products' (2011) 8(4) JEEPL 353

ply only to the finished article and not to its individual components.

However, on 8 June 2011, France (one of the seven countries to dissent) issued a 'Notice' that referred to the ECHA guidance on articles set out above. The stated purpose of the French Notice was, "to inform economic operators of the interpretation adopted in France for the purpose of the application of Articles 7.2 and 33 of the REACH Regulation." The Notice set out the view that an article,

> "might be composed of one or several objects which meet the definition of 'article', and the provisions laid down in Articles 7.2 and 33 are therefore to apply to each of them."

This view was the basis on which the French authorities would enforce REACH, a view contrary to that put forward in ECHA's guidance.

III. The Facts of the Case

FCD and FMB brought an action against the Notice of 8 June 2011 before the Conseil d'Etat. They argued that the Notice was based on an understanding of "article" which went against the Commission Note and ECHA guidance. FCD and FMB argued that ECHA was empowered under Article 77 of REACH to provide guidance in relation to articles,[15] and that the French interpretation hindered the uniform implementation of REACH as well as raising issues of legal certainty.[16] These arguments were generally supported by the Commission, which additionally argued that the French authorities would need to provide valid grounds (as required under Article 114 TFEU) if they wished to depart from the harmonizing effects of Article 33 of REACH.[17]

The Conseil d'Etat referred the question of whether the obligations in REACH under Articles 7(2) and 33 applied to assembled articles or the constituent elements of the article to the Court of Justice for a preliminary ruling. Ireland and Greece supported the arguments of the Commisison, FCD and FMB. France, Belgium, Denmark, Germany, Austria, Sweden and Norway (the seven countries which opposed the ECHA guidance) took the opposite line.

IV. The Court's Ruling

The Court in its ruling broadly followed the Opinion of Advocate General Kokott. The Court saw some of the arguments raised by FCD and FMB, and the Commission, as asking it to rule on the compatibility of the French Notice of 8 June 2011, which it was not prepared to do.[18] Moreover, the Court took the line that the fact that the approach in the French Notice was contrary to the approaches in the ECHA guidance and Commission Note, "is not relevant for the purposes of the" proceedings.[19] The role of the Court was to provide the Conseil d'Etat, "with guidance as to the interpretation of the REACH Regulation, in order to enable it to determine whether EU law requires it to disapply national rules governing the interpretation of that regulation."[20]

Having reviewed the Regulation, the Court set out three factors that are relevant to whether an object could be classified as an "article" under REACH.[21] First, an "article" is something that has undergone "production", and is thus "manufactured...in contrast to objects in their natural state." Second, the production process must give the object "a special shape, surface or design" which, and third, "must be more decisive for the function of the object in question than its chemical composition." These three factors are, with respect, simply a rehearsal of the definition of "article" from Article 3(3) of REACH. They add almost nothing to the Regulation.

1. "Complex Articles"

The Court then turned to the question of a "complex article", an article that is made up of other articles. Noting that REACH does not contain any specific provisions on complex articles, the Court suggests that this "legislative silence must be construed" in light of the "principle objective" of REACH which is:

> "not to regulate all manufactured products, but to monitor the chemical substances present by themselves or in a mixture as well as, in certain cases,

15 Judgment, para 23
16 Judgment, para 23
17 Judgment, para 24
18 Judgment, para 25
19 Judgment, para 27
20 Judgment, para 26
21 Judgment, para 47

> particularly those listed restrictively in Article 7 thereof, when they are contained in articles."[22]

As a result, the Court saw "no need" to draw a distinction between articles incorporated as elements of a complex article, and articles by themselves.[23] The only question was whether, "a complex product itself may be classified as an article" under Article 3 of REACH.[24] Here, the Court noted that REACH was also silent on the question of whether, or if, an object which meets the definition of "article" can then cease to be an "article".[25] As such, when an article is "assembled or joined with other objects to form a complex product" that original article continues to be an article.[26] This, the Court held, is on the basis that the original article retains a special shape, surface or design which is more decisive for its function than its chemical composition, and as long as the original article does not become waste.[27]

2. The Notification Obligation and the 'Right to Know'

Having settled the question of complex articles, the Court turned to the duty of notification in Article 7(2) of REACH. It was clear to the Court that that duty, "concerns only those articles which [producers] make or assemble themselves."[28] This conclusion was reached by the Court through reference to Recital 29 of REACH, and the use of the possessive adjective "their" in that Recital.[29] Such meant that the notification duty could not apply to an article made by a third party that was used by the producer "as input."[30] Examining the function of Article 7(2) in the light of the wider purposes of REACH, the Court comments that the notification obligation exists "in order to avoid an information deficit about the use of substances of very high concern."[31]

In relation to Article 33 – the "right to know" provision – the Court said that this was "distinct in a number of respects" to the Article 7(2) obligation.[32] This was because Article 33 applied to all operators along the supply chain, and because the "purpose" of Article 33 was different.[33] Here, the Court said that Article 33:

> "whilst contributing towards the attainment of the general objective of ensuring that human health and the environment are not adversely affective is...aimed at enabling all operators in the supply chain to take, at their stage, those risk management measures which follow from the presence of substances of very high concern in articles in order to guarantee their completely safe use."[34]

This Court goes on to reference the "supply choice" given to supply chain operators and consumers that is an "indirect" aim of Article 33, and the objective of REACH to progressively replace SVHCs with suitable alternatives.[35] The "conjunction of these factors" meant that the Article 33 duty to provide information flowed along the supply chain, following the article to the final consumer.[36] As such, it would be "incompatible" were the introduction of an article along the supply chain be capable of interrupting the duty to provide information.[37] The Court was not persuaded that this interpretation was disproportionate and, rather, called the threshold substance of the obligation in Article 33 "minimal in nature" (i.e. the requirement to supply, as a minimum, the name of the SVHC). The result of this analysis was that Article 33 meant that,

> "it is for the supplier of a product one or more constituent articles of which contain(s) [a SVHC...] in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance."[38]

As such, the Court took the "once an article, always an article" approach that had been put forward by the seven countries that disagreed with the ECHA

22 Judgment, para 49
23 Judgment, para 50
24 Judgment, para 50
25 Save as regards when articles become waste. See Article 2(2) of REACH. Judgment, para 52.
26 Judgment, para 53
27 Judgment, para 53
28 Judgment, para 55
29 Judgment, para 56
30 Judgment, para 57
31 Judgment, para 60
32 Judgment, para 75
33 ibid
34 Judgment, para 77
35 Judgment, para 78
36 Judgment, para 79
37 Judgment, para 80
38 Judgment, para 82

guidance. FCD and FMB argued that an interpretation of an 'article' to include composite parts would have considerable burdens: complexities for suppliers and importers in determining SVHC concentrations; and the challenging practicalities of obtaining detailed information on complex supply chains from producers outside the EU.[39] The Court, however, was unsymaptheic: "Difficulties of that nature, however, do not affect the interpretation of...the REACH Regulation."[40]

The ruling in this case is a literal approach taken by the Court based on the specific wording of REACH and on the lack of specific reference in the Regulation to complex articles made up of other articles. The practical impacts of the Court's ruling mean a significant increased compliance burden (i.e. a requirement for greater granular data on all finished articles made up of other articles), and a potential corollary increase in the number of notifications and safe use notices. ECHA has since placed a front page to its 'substances in articles' guidance to say that the document will soon be updated to reflect the Court's ruling, which ECHA says, "clarifies the scope of substances in articles notification (Article 7(2)) and communication (Article 33) obligations and how the concentration limit (0.1 % w/w) should be interpreted."

V. A Battle of the Norms

For the first time, the Court in this case comments on the nature of ECHA guidance. This is not insignificant. As set out above, ECHA has produced more than one million words of guidance to accompany REACH. Previous cases on REACH have only paid passing attention to these norms. In the present case the Court held:

> "Given the legislature's intention [in conferring guidance making powers on ECHA], a document such as the ECHA Guidance document may be one of the factors to be taken into consideration in interpreting the REACH Regulation."[41]

The Court did not set out what the other factors might be. It did go on to say that, "a document of that nature [i.e. a guidance document] remains purely explanatory" and that the interpretation given in it of provisions of REACH, "is of no legislative effect whatsoever."[42] This is almost wholly meaningless, except insofar as it conveys the message "This Court decides". In other research, I have reviewed every piece of ECHA guidance.[43] This review clearly shows that that guidance does more than merely explain the content of REACH: at times, it channels the actions of registrants down paths not set out in REACH; on other occasions it 'gap fills' where REACH is silent; and finally, but admittedly less often, ECHA guidance directly contests and goes against the drafting of REACH. This is all in addition to the way in which ECHA guidance amplifies, or explains, the text of the Regulation. Equally, the "effect" of guidance operates in realms other than the legislative. There is good reason to consider the practical effects of guidance on those to whom it is addressed. I would further suggest that the Court paid too little attention in this case to the ways in which post legislative norms may have various binding effects, and ignored important Court of Justice jurisprudence on just that point.[44] This is particularly true in the case of guidance issued by public bodies (the Commission, ECHA etc) but there are equally interesting and important questions about post legislative guidance issued by private bodies (e.g. Cefic, REACH SIEFs). There is also the associated problem that, as Bergkamp and Herbatschek put it, "the rejection of ECHA's guidance is a slap in [ECHA's] face and undermines the authority of its guidance generally."[45] It would be interesting to empirically explore whether the Court's ruling in this case impacts on the way in addressees understand ECHA's guidance (and, so whether the ruling has unintended legal certainty implications).

As part of its consideration of the ECHA guidance, the Court references: (i) the 'Legal Notice' which is "set out expressly in a preliminary section in the ECHA Guidance document" and which states that the guidance has "no legal value" as the text of REACH

39 Judgment, para 44

40 Judgment, para 68

41 Judgment, para 28

42 Judgment, para 28

43 S. Vaughan, EU Chemicals Regulation: New Governance, Hybridity and REACH (Edward Elgar, 2015)

44 See, for example: Case C-325/91 *France v Commission* [1993] ECR I-3283, Case C-226/11 *Expedia Inc v Competition Authority* [2012] ECR I-795, Case T-187-99 *Agrana Zucker v Commission* [2001] ECR II-1587; Case T-214/95 *Vlaamse Gewest v Commission* [1998] ECR II-717; and Case C-520/09 P *Arkema v Commission* [2011] ECR I-08901

45 Bergkamp and Herbatschek, n 13 above, 159

is "sole authentic legal reference:"[46] and (ii) the "Note to Reader" on the front cover to the ECHA guidance on articles which says that it was not fully supported by all Member States. However, the Court does not go on to say why the "Legal Notice" and "Note to Reader" are relevant. Not every piece of ECHA guidance contains a "Legal Notice",[47] and the 'substances in articles' guidance document is the *only* ECHA guidance with a "Note to Reader." Where neither of these are present, does ECHA guidance have a different normative quality?[48] Given the breadth and depth of ECHA's guidance, the Court in this case had an opportunity to effectively engage with the realm of post legislative norms in EU chemicals regulation space. That opportunity was sadly missed.

46 Judgment, para 29

47 Vaughan, n 43 above

48 For a more detailed review of these issues, see: S. Vaughan, 'Differentiation and Dysfunction: An Exploration of Post-Legislative Guidance Practices in 14 EU Agencies' (2015) 17(1) *Cambridge Yearbook of European Legal Studies* 66