Case Note

The Case Notes section will identify and analyse important judgements of courts around the world that shape the interpretation and application of chemical law and regulation.

The Spring 2019 REACH Authorisation Cases: Lessons to Learn for REACH Authorisation Applicants

Case T-837/16 Sweden v European Commission
Case T-108/17 Client Earth v European Commission

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I. Introduction

In February, March and April of this year (2019), there were several important decisions regarding REACH Authorisation. These spring 2019 decisions – some of which were handed down by the EU General Court, others of which the European Commission adopted – offer important insights, and valuable lessons, on how applicants should compile REACH Applications for Authorisation, and how ECHA and the Commission should review those applications. At the time of writing, there are reports that some of these decisions shall be challenged or appealed. There may, therefore, still be further points for applicants for REACH Authorisation to learn from these cases. The aim of this article is to briefly highlight some of the main points in the spring 2019 REACH Authorisation de-

cisions. In particular, this article summarises some of the core points addressed in: (1) Case T-837/16 Sweden v European Commission (the ‘*Swedish case*’); (2) Case T-108/17 Client Earth v European Commission (the ‘*Client Earth case*’); and (3) the first European Commission decision rejecting an Application for REACH Authorisation (the ‘*HAPOC case*’).

II. REACH Authorisation: Background

One of the key political drivers behind the adoption of the REACH Regulation, was to make industry responsible for demonstrating safe use of chemicals (‘reversal of the burden of proof’)¹. Although REACH Registration is one of the principal means by which the reversal of the burden of proof is achieved – it is the REACH Authorisation provisions which more fully and more comprehensively implement this core objective in practice.

The underlying objective of the Title VII REACH Authorisation provisions is to prohibit the sale and use of Substances of Very High Concern (‘SVHCs’) by ensuring that they are progressively replaced by suitable alternative substances, technologies or techniques². The general principle codified in the REACH Title VII provisions is that: where a substance is included in Annex XIV REACH and the sunset date has passed, the Annex XIV substance can only be placed on the market or used in the EEA if a company or other relevant entity in the supply chain,³ has obtained a valid REACH Authorisation and the conditions of

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1 See, for example, Art 1(3) of the REACH Regulation, which states: ‘This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.’

2 See, to that effect, Art 55 of the REACH Regulation.

3 Arts 56(2) and 56(1)(e) REACH.

the Authorisation cover the use. As a result, whereas REACH Registration is the figurative legal key used to gain access to the EU/EEA market, in contrast REACH Authorisation is the figurative legal shield which stops the general Annex XIV prohibition from having an effect, for a certain period of time. Some commentators have described REACH Authorisation as a form of 'REACH Registration in reverse'⁴.

There are generally two routes for an applicant to obtain REACH Authorisation for a specific substance and use combination. If an applicant is able to prove that the risk to human health or the environment from the use arising from the intrinsic properties is adequately controlled – an Authorisation must be granted.⁵ If an applicant is able to prove that the socio-economic benefits arising from the use of the substance outweigh the risk to human health or the environment, and if there are no suitable alternative substances or technologies – an Authorisation may be granted.⁶ The Swedish case, and the Client Earth case, shed important light on what applicants should include in, and how the ECHA and the Commission should assess, applications for REACH Authorisation.

III. Case T-837/16 Sweden v European Commission - The 'Swedish Case':

1. The Facts of the Swedish/DCC Case

On 19 November 2013, a REACH Only Representative (DCC Maastricht BV) submitted applications for Authorisation for two lead chromates, both of which were a mixture of lead and chromium VI elements. The applicant applied for uses for each substance included the same 6 uses. All 6 uses related, directly or indirectly, to use in certain pigments, paints and other products. Approximately 100 downstream users formed part of the associated supply chains. In its applications for authorisation, the applicant provided, amongst other things, an analysis of alternatives comparing the properties of each of the Annex XIV substances to more than 30 substances and indicated that none of these substances in its view met the technical properties of the pigments involved.⁷

During the public consultation period,⁸ some stakeholders⁹ argued that: there were appropriate and safer alternative substances which were available; that these alternatives had been commercially

available around the world for many years; and that the alternatives could be used to obtain product specifications and desired performance at reasonable cost. These stakeholders therefore disagreed with the applicant, that the uses of the Annex XIV lead chromates were irreplaceable for industry or the applicant.

On 11 December 2014, the ECHA Committee for Risk Assessment ('RAC') and the ECHA Committee for Socio-economic Analysis ('SEAC') adopted consolidated opinions regarding the 6 uses for each substance. The Court noted that the SEAC had concluded that, as regards the analysis of alternatives: (1) for 2 of the 6 uses, the applicant had not provided an analysis of alternatives and that, at the 'formulation stage', the pigments in questions appeared to have no function meaning that an analysis of alternatives could not, apparently, be performed; (2) for 2 other of the 6 uses, the SEAC essentially listed the Applicant's opinions on the one hand, and the opinions of some other stakeholders on the other – which were contradictory and not aligned; (3) for the 2 other remaining uses of the 6 uses applied for, the SEAC had essentially concluded that there were uncertainties and that the uncertainty regarding alternatives should be taken into account 'when fixing the review periods'. The Court also noted that the SEAC had concluded that, in the SEAC's opinion, it 'seemed' that there were no alternatives for the applicant.

On 7-8 July 2015, 22-23 September 2015 and 4 February 2016 – the application was discussed within the European Commission REACH Committee. 2 EU Member States, and also Norway, indicated that the lead chromates were not used in pigments in their national territories in some areas, such as road markings – with one EU Member State having banned the use of lead chromates for road markings more than 20 years ago. Despite the points from Sweden, Nor-

4 Meaning that REACH Authorisation should not be regarded as a legal means of unlocking, or gaining access, to a market – but a legal means of temporarily locking out, or stopping, an Annex XIV ban having effect in a particular area; Gailen A Hart (ed), *Professional Practices of Product Stewardship* (Product Stewardship Society 2018) 209.

5 Art 60(2) of the REACH Regulation.

6 Art 60(4) of the REACH Regulation.

7 Case T-837/16 *Sweden v European Commission* ECLI:EU:T:2019:144, Para 88.

8 Held pursuant to Art 64(2) REACH.

9 Particularly the British Coatings Federation and others.

way and others, the REACH Committee voted in support of the applications.¹⁰

On 7 September 2016, the European Commission adopted an Implementing Decision granting REACH Authorisation for certain uses of the lead chromates. The Decision stated, amongst other things, that due to the difficulties in fully establishing the unavailability of alternatives it was appropriate to set the review periods at an earlier date and/or to refine the description of the uses which were authorised. The Decision also precluded the ability of using the substances in Member States whose national laws prohibited the use of lead chromate in road markings.

On 28 November 2016, Sweden lodged an application with the General Court seeking annulment of the European Commission Decision. Sweden was supported by Denmark, Finland and the European Parliament.

2. General Court Judgment in the Swedish/DCC Case

Although Sweden raised a number of pleas, the Court focused primarily on Sweden's first plea, specifically: that the European Commission had erred in law,

and acted in breach of Article 60(4) REACH by granting authorisation without it being duly established that there were no alternatives; that the Commission had failed in its duty of care in determining whether there were viable alternatives; and that the Commission had wrongly attempted to remedy the deficiencies contained in the analysis of alternatives by shortening the review periods and refining the conditions of authorised use.

The General Court first stated that, the Commission was correct to conclude that the only legal basis which would allow adoption of the Contested Decision, was authorisation granted pursuant to Article 60(4) REACH – ie via the socio-economic route.

The Court then held that it was 'for the Commission alone to determine whether the conditions [set out in Article 60(4) were] met' and that the Commission alone was therefore required to examine the relevant information. The Court pointed out that the Commission could not act as an 'arbiter' whereby the Commission could limit the Commission assessment and decision to the evidence or information provided by certain actors in the REACH Authorisation procedure.¹¹ As such, the conclusion drawn by the Court was that, pursuant to Article 60(4), the Commission itself was required: to conduct a review; adhere to the principle of sound administration; and had a duty of care to establish itself what the relevant facts and circumstances were.¹² The Court also noted that although the Commission was required to 'take into account'¹³ the opinions of the RAC and SEAC which have valuable scientific advice,¹⁴ the Commission was not legally bound by such advice¹⁵ and that the Commission could not reproduce or substitute its own assessment with that of the ECHA Committees^{16,17}.

Having confirmed that the Commission itself was legally required to conduct a complete and independent assessment of whether the Article 60(4) conditions were met,¹⁸ the Court then turned to issue of the analysis of alternatives. As a preliminary point, the Court clarified the meaning and scope of the term 'alternatives', and the related obligations under the Title VII provisions.

First, the Court addressed what would constitute a 'suitable alternative' for the purposes of Article 55 and 60(4). Referring to paragraph 73 of the Preamble, the Court held that the term 'suitable' tended to limit the number of substances, technologies or techniques which may constitute a relevant and 'suitable alternative'. The Court held that 'suitable alternatives'

10 23 EU Member States voted in favour of the applications, with 3 EU Member States voting against the applications, and 2 EU Member States abstaining.

11 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 64.

12 *ibid* Para 64.

13 *ibid* Para 65.

14 *ibid* Para 66.

15 *ibid*.

16 *ibid* Para 67.

17 The Court concluded that where there is no information to 'cast serious doubt' on an ECHA Committee Opinion – that may, in principle, be sufficient to enable the Commission to grant or reject an application for authorization – without more scientific review by the Commission being undertaken – Para 67. Where the Commission agrees and endorses an ECHA Committee Opinion, the Court stated that the Commission must still 'verify the completeness, consistency and relevant reasoning' in the notice – Para 68. Where the Commission disagrees or deviates substantially from an ECHA Committee opinion, or substitute its own (Commission's) view on a technical or economic issue – with the view of the ECHA Committee, the Commission must 'give specific reasons for its assessment' and the justification must 'be of a scientific level at least equivalent to that of the opinion in question' – Para 69.

18 An assessment which the Commission, alone, must conduct – involving an examination of the relevant facts and information, and not limited to the information or arguments provided by the applicant or other stakeholders.

would, in principle, only include those alternatives which provided a 'safer' solution to the use of the Annex XIV substance.¹⁹ This point itself will be of significant interest to future applicants for REACH authorisation, who will now rightly question whether they should first assess: (1) whether a particular 'alternative' provides a 'safer solution' and - if it does not; (2) then discount that 'alternative' from the analysis of suitable alternatives – or at least presume the 'alternative' has lesser importance in the analysis of alternatives assessment.

Second, the Court provided clarification on the meaning of 'economically and technically viable' for the purposes of Article 55²⁰ stating that the analysis of alternatives should be limited to alternatives in terms of 'production capacity of these substances and the feasibility of these technologies, as well as with the legal and factual conditions of their release.'²¹ The Court stated that 'alternatives' which were merely alternatives '...in the abstract or in laboratory conditions or in conditions which are only exceptional' would generally not constitute 'economically and technically viable' alternatives.²²

Third, the Court clearly stated that an alternative must be technically and economically feasible 'to the applicant' of the authorisation.²³ Even if, ECHA were to conclude²⁴ that an alternative existed, but that alternative was not 'technically or economically feasible for the applicant in question' – the Court held that it would not 'necessarily imply' that the Commission should refuse to grant the Article 60(4) authorisation.²⁵ In other words, where an alternative

exists, and industry is generally of the opinion that the alternative is 'technically and economically viable'²⁶ – it is still legally possible for a specific applicant to rebut the presumption that the alternative is 'technically and economically viable' to the applicant company in question, and therefore it is legally possible for the Article 60(4) conditions to be satisfied and for the applicant to obtain a REACH Authorisation. Under these circumstances, the Court added that an applicant would also generally be required to provide a Substitution Plan in accordance with Article 62(4)(f) REACH.^{27,28}

Lastly, the Court made clear that although the Commission is required to ensure that the legal conditions under Article 60(4) are satisfied²⁹ – ultimately the applicant for authorisation bears the full burden of proof, and the full responsibility, of demonstrating that no suitable alternative is available to the applicant in question.³⁰ The Court stated that if, despite all the information gathered by the Commission and provided by the applicant, there are still 'uncertainties' as regards the 'unavailability of alternatives': 'it must be concluded that the applicant has not satisfied the burden of proof and that, therefore, authorisation cannot be granted.'³¹

The Court then turned its attention to the division of responsibilities in the REACH Authorisation process, and, in particular, what REACH applicants for Authorisation are legally required to provide in their applications, and what the Commission and ECHA are legally required to do when reviewing those applications. Importantly, on this point the

19 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 72.

20 Art 55 of the REACH Regulation states: 'The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.:'; Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Paras 73-75.

21 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 73.

22 It should be noted that even where an alternative may not be 'available' per se to an applicant, an applicant would still be expected to consider in its application, amongst other things, the changes that may be needed to ensure or enable possible alternatives to become 'available' in the future.

23 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Paras 74- 75. Note references to Art 60(5)(b) REACH.

24 Either on the basis of information ECHA itself has obtained or generated, or on the basis of information which ECHA had received during a public consultation

25 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 75.

26 And, therefore the Art 60(4) conditions are not met, and applications for authorisations should be denied.

27 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 76.

28 Some commentators may question the ability to provide a meaningful Substitution Plan if the alternative is not available to the Applicant in the first place, and the Applicant has fully discharged his burden of proof, erasing all relevant uncertainty, on the unavailability of an alternative.

29 The Commission is required to ensure that it conducts its own assessment of the facts and information in order to ascertain whether the legal conditions of Art 60(4) are satisfied.

30 Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 77.

31 *ibid* Para 79.

Court concluded that the Commission cannot ‘correct deficiencies of an application for authorisation’ by adapting the conditions of the authorisation, in particular the review period or the authorised conditions.³² Where there was contradictory information on whether suitable alternatives were available – the Court held that the Commission was required, pursuant to its duty of care, to examine the conditions on the unavailability all the more thoroughly.³³ The Court also stated that the Commission cannot adopt a decision permitting a REACH Authorisation ‘based on simply unconfirmed assumptions or invalidated by the information available to it.’³⁴

In the case in hand, the Court ultimately concluded that, at the date of the adoption of the Contested Decision there was nothing to demonstrate ‘the unavailability of appropriate substances or alternative technologies’³⁵, and that the review by the Commission ‘had not been properly completed.’³⁶ The Court concluded that ‘the Commission granted approval without first checking a sufficient number of substantial and reliable information to conclude whether alternatives were lacking for all uses applied for and that uncertainties still remained on the date the Contested Decision was adopted.’³⁷ Although the Court acknowledged that the applicant’s analysis of alternatives for the Annex XIV substances involved a comparison with more than 30 other substances,³⁸ the Court stated that the submissions made by Member States and other third parties in the REACH Authorisation procedure ‘cast serious doubts on the analysis submitted by the applicant.’³⁹ The Court noted a number of defects made by the ECHA SEAC and

the Commission regarding the assessment and conclusion of the purported unavailability of alternatives⁴⁰. And, therefore concluded that, amongst other things, there had been ‘insufficient examination of the conditions [set out in Article 60(4)].’⁴¹

On that basis, the Court annulled the Commission Decision granting DCC Maastricht BV REACH Authorisation to place on the market and use the lead chromates for the respective uses.

3. Legal Analysis of the Swedish/DCC Case

There are a number of points in the Judgment of core significance to both the EU authorities (in particular the Commission and ECHA) and to applicants for REACH authorisation.

a. Commission – Independent Examination of Whether Authorisation Should be Granted

First, the Judgment in the Swedish case makes clear that the Commission cannot simply adopt or rubber-stamp ECHA Committee opinions regarding REACH Authorisation Article 60(4) applications. In essence the Court concluded that the Commission must examine and decide whether a REACH Authorisation should be granted to an applicant – independently and on its own – and separately to ECHA and the ECHA Committees. The Commission cannot simply rely on ECHA, or the ECHA Committee opinions, in deciding whether an application for authorisation should be granted. The Commission must carry out its own examination of the facts and circumstances. The Commission’s examination must comply with the legal principle of sound administration. And the Commission has a duty of care in establishing itself what the relevant facts and circumstances are.

This is important. It means that the Commission itself must be more proactive in establishing what the underlying facts regarding a particular application for authorisation are,⁴² and whether the legal conditions have been satisfied by an applicant.

And the Court Judgment has the potential to have serious repercussions in practice. It could, for example, lead to a situation where there is more divergence of opinion between, on the one hand, ECHA and its Committees, and, on the other hand the Commission. It could mean, for example, that the ECHA and its

32 *ibid* Para 82.

33 *ibid* Para 84.

34 *ibid* Para 81 (Unofficial translation of the French text).

35 *ibid* Para 86.

36 *ibid* Para 86 (Unofficial translation of the French text).

37 *ibid*.

38 *ibid* Para 88.

39 *ibid* Paras 88-92.

40 *ibid* Paras 93-98.

41 *ibid* Paras 104.

42 It can be argued, perhaps, that the Commission has looked – at least to some degree – at these issues in the past, and has, for example, refined conditions of authorized use so that REACH applications granted by the Commission were slightly different to the authorized uses recommended by the ECHA Committee but, in this case, the Court was clear that the Commission assessment was not deep, extensive or apparently autonomous enough.

Committees might take the view that an applicant for authorisation should be granted authorisation – but the Commission could, despite the ECHA’s view, deny and reject the applicant’s request. This is a cause for concern for applicants for authorisation. Applicants will be reluctant to invest significant time, effort and money in compiling applications, if there is a significant risk that the application will be ultimately denied by the Commission regardless of what ECHA has concluded. Applicants will be particularly reluctant to invest significant time, effort and money in compiling applications – without having at least some idea of what the Commission itself – rather than ECHA – wants to see in an application for authorisation.

However, in the Swedish case, the Court Judgment did not merely state that the Commission itself was required to conduct an independent examination of the factual and legal circumstances. The Judgment also went on to outline if, and when, the Commission could contradict or ignore an ECHA recommendation or conclusion. The Court stated, for example, that the Commission is legally required to take into account the opinions of the ECHA Committees. More significantly, the Court Judgment also went on to state that: where there is sufficient information to ‘cast serious doubt’ on an ECHA Committee Opinion – that may, in principle, be sufficient to enable the Commission to grant or reject an application for authorisation – without more scientific review by the Commission being undertaken.⁴³ Where the Commission agrees and endorses an ECHA Committee Opinion, the Court stated that the Commission must still ‘verify the completeness, consistency and relevant reasoning’ in the notice.⁴⁴ Where the Commission disagrees or deviates substantially from an ECHA Committee opinion, or substitute its own (Commission’s) view on a technical or economic issue – with the view of the ECHA Committee, the Commission must ‘give specific reasons for its assessment’ and the justification must ‘be of a scientific level at least equivalent to that of the opinion in question.’⁴⁵

In sum, in the Swedish case, the Court concluded that the Commission had failed to conduct a sufficiently independent and thorough examination of whether the application should have been granted. This will no doubt have real consequences in reality – prompting the Commission to conduct more independent, thorough and autonomous examinations of whether other applications for authorisation in the

future should be granted. However, at the same time, the Court outlined a number of points, which would seem to make it more difficult for the Commission to diverge from an ECHA recommendation or conclusion – and therefore may seem to ‘tie the Commission’s hands’ more tightly to follow an ECHA view. Commentators will no doubt have their own views on where the legal boundary lies between what the Commission is legally required to do, and what the Commission is able to do, following an ECHA opinion regarding a particular REACH application for authorisation. In any event, and regardless of that debate, the Judgment in the Swedish case apparently calls into question the legality of previous Commission’s decisions granting or rejecting applications for authorisation in the past⁴⁶.

b. Commission – Cannot Grant Authorisation, or Rectify, where Applications are Incompliant

Second, the Judgment in the Swedish case highlights the fact that the legal requirements regarding applications for authorisation must be satisfied in full. There is no ability for the Commission to conclude that an application is compliant and complete, if relevant information is regarded as missing or incomplete. The Commission cannot grant a REACH Authorisation if, for example, there are significant doubts as to the unavailability of alternatives. Where the Commission believes information is incomplete or missing, the Commission is not legally able to rectify or remedy the application by, for example, granting authorisation while reducing the review periods or refining the authorised conditions of use.

c. More Legal Challenges Regarding Annex XIV or Candidate Listing in the Future?

Ultimately the Court held in the Swedish case, that the Commission had wrongly granted REACH Au-

⁴³ Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 67.

⁴⁴ *ibid* Para 68.

⁴⁵ *ibid* Para 69.

⁴⁶ It also calls into question some of the recent decisions adopted by the Commission relating to REACH Authorisation, including the decision denying, for the first time, a company REACH Authorisation to use an Annex XIV substance, specifically the Commission decision denying HAPOC GmbH & Co KG the use of sodium dichromate in a particular (molten bath) form for the treatment of certain medical instruments for micro-surgery.

thorisations to the applicant, and consequently annulled the Commission decision granting those Authorisations. The Court judgment therefore raises a number of concerns to many in industry, as it appears to make it more difficult for applicants to obtain REACH Authorisation in practice. As such, the Swedish case does not merely illustrate the powerful Scandinavian influence on EU chemicals policy and implementation.⁴⁷ It also apparently signals the hardening of attitudes against certain apparent policies surrounding the grant of REACH Authorisation. Until now, many in industry have opted not to take legal action against Annex XIV listings, or Candidate Listing, on the understanding that REACH Authorisations could and would likely be granted, at least in the short term, and that there would be some tolerance of the first applications for authorisations submitted as ECHA, and others were 'learning while doing'. The Swedish case may force industry to re-visit, and re-assess, this general view.

d. Court Judgment Creates a Burden-of-Proof Requirement which Some Companies May Not be Able to Satisfy

There are also other concerning aspects about the Swedish case for industry. The notion that if there are any uncertainties regarding the unavailability of alternatives, the applicant has not satisfied the burden of proof, and therefore a REACH authorisation must be denied – may appear to some, to go too far. There may always be some residual uncertainty regarding the unavailability of alternatives. If the burden of proof upon an applicant is to convince the Commission and ECHA until they are 'certain' of the unavailability of suitable alternatives to a particular applicant – the legal threshold may seem simply too high to satisfy in practice. The onerous nature of the burden of proof placed upon applicants will be particular concerning to SME companies with limited resources or time. The Court judgment in the Swedish case comes after many in industry have already voiced concerns about the time and expense involved in obtaining REACH Authorisations.

Also, in this Swedish case, the fact that some stakeholders submitted comments which, in the Court's view, cast 'serious doubts' on the applicant's analysis of alternatives, was of clear importance in the case. REACH applicants for authorisation may now therefore fear that, if stakeholders raise any doubts during the public consultation process, it may, in the Commission and ECHA's mind, create 'uncertainties' sufficient enough to prevent the Commission from granting the applicant REACH Authorisation. The Swedish case therefore raises questions as to whether REACH applicants for authorisation should now respond, in full, to all comments made by all stakeholders during the REACH application for authorisation procedure, to ensure no relevant doubts are sown in ECHA's or the Commission's mind. Again, whether SME companies can really be expected to take on this type of administrative burden is a question, although, in principle, there should also be equal treatment.

Although the Judgment in the Swedish case, which was handed down in March 2019, raises a number of concerns for industry, it should be noted, that certain aspects of the Judgment are currently, at the time of writing, being appealed. Also, the Judgment in the Swedish case should be understood in light of another important and recent Judgment.

In April, the General Court handed down its judgment in the Client Earth case – which also focused primarily on the REACH Authorisation provisions. Whereas, in the Swedish case, the Court held that the Commission was wrong to have granted REACH Authorisation to an applicant for certain lead chromates, in the Client Earth case the Court held that there were no valid legal grounds to question the REACH Authorisation granted by the Commission to certain waste recyclers for uses relating to recycled PVC materials and DEHP. Whereas the Swedish case arguably make it more difficult for applicants to obtain REACH Authorisation, the Court's Judgment in the Client Earth case arguably contains at least some positive points for applicants.

IV. Case T-108/17 Client Earth v European Commission - The 'Client Earth Case'

1. The Facts of the Client Earth Case

On 17 February 2011, the European Commission included bis(2-ethylhexyl) phthalate ('DEHP') on An-

⁴⁷ The Swedish case was brought before the Court by the Kingdom of Sweden and supported by Denmark and Finland, as well as the European Parliament.

nex XIV REACH on the basis of reproductive toxicity.⁴⁸

On 13 August 2013, three waste recycling companies submitted a joint application for authorisation to use DEHP in: (1) the formulation of recycled soft poly(vinyl chloride) ('PVC'); and (2) industrial use of recycled soft PVC containing DEHP in polymer processing.⁴⁹ In their application for authorisation, the applicants provided, amongst other things, an analysis of alternatives and stated that: 'DEHP d[id] not have a specific functional role for them.'⁵⁰ DEHP was considered as merely present as a largely unwanted ingredient or impurity in the waste which they collected and subsequently recycled.⁵¹

In October 2014, the ECHA Committee for Risk Assessment (RAC) and the ECHA Committee for Socio-Economic Analysis (SEAC) issued their opinions on the application for authorisation. RAC and SEAC concluded that the application for authorisation could be granted pursuant to the socio-economic route. However, the SEAC noted that there were 'certain deficiencies' in the analysis of alternatives,⁵² in particular: (i) deficiencies in demonstrating the socio-economic benefits of the applied for uses; and (ii) deficiencies of the 'qualitative analysis' of alternatives addressing relevant uncertainties⁵³.

On 12 December 2014, ECHA updated the listing for DEHP on the Candidate List of substances identified as SVHCs, as a substance with endocrine-disrupting properties which gave rise to an equivalent level of concern pursuant to Article 57(f) REACH.

On 16 June 2016, the Commission granted the applicants authorisation for two uses⁵⁴ on the condition that the content of DEHP in recycled soft PVC in compounds and dry-blends did not exceed 20%.⁵⁵ The review periods were fixed at 4 years.⁵⁶ The Commission also imposed monitoring arrangements.⁵⁷ In the recital of the Authorisation Decision, the Commission stated that REACH '...d[id] not apply to waste...' and that the REACH authorisation therefore only applied 'to the extent that those compounds and dry-blends ha[d] ceased to be waste [in accordance with Article 6 of Directive 2008/98/EC].'⁵⁸

On 2 August 2016, Client Earth sent a letter to the Commission requesting the Commission to conduct an 'internal review' of the authorisation decision pursuant to Article 10 of Regulation (EC) No 1367/2006 ('Aarhus Access to Information Regulation').⁵⁹ On 7 December 2016, the Commission adopted a decision rejecting the Client Earth request.⁶⁰

On 17 February 2017, Client Earth lodged an application with the General Court seeking annulment of the European Commission Decision rejecting the Client Earth request for an internal review under the Aarhus Access to Information Regulation⁶¹. In addition, Client Earth also indirectly requested the Court to annul the European Decision granting authorisation. Client Earth argued that although Client Earth did not have legal standing to challenge the Commission Decision to grant authorisation itself,⁶² if the Court annulled the Commission decision rejecting the Client Earth request for an internal review – the 'logical consequence' would be for the Court to also annul the Commission decision granting REACH Authorisation⁶³ and cited to Article 266 of the TFEU.⁶⁴

As such, Client Earth in essence challenged the Commission Decision to grant REACH Authorisation to the three waste recycling companies for the 2 uses of DEHP, but Client Earth did this via – or through – the subsequent, and separate, Commission Decision rejecting the Client Earth request for an internal review pursuant to the Aarhus Access to Information Regulation. The General Court Judgment therefore assessed the REACH Authorisation provisions, but through the prism of the initial rejection by the Commission of Client Earth's request for an internal review pursuant to the Aarhus Access to Information Regulation.

48 Commission Regulation (EU) No 143/2011.

49 Case T-108/17 *Client Earth v European Commission* [2019] ECLI:EU:T:2019:215, Para 2.

50 *ibid* Para 4.

51 *ibid*.

52 *ibid* Paras 5-6.

53 *ibid* Para 5.

54 Implementing Decision C(2016) 3549 ; Paras 9, 84, 60, etc.

55 Case T-108/17 *Client Earth v European Commission* [2019] ECLI:EU:T:2019:215, Para 10.

56 *ibid* para 11.

57 *ibid*.

58 *ibid* Para 13.

59 *ibid* Para 14.

60 *ibid* Paras 15 – 17.

61 *ibid* Para 16.

62 *ibid* Para 26.

63 *ibid* Para 27.

64 *ibid* Para 30.

2. General Court Judgment in the Client Earth Case and Legal analysis

a. Can NGOs Legally Challenge a Commission Decision Granting a Company REACH Authorisation?

Before assessing the main arguments in the case,⁶⁵ the Court addressed whether Client Earth's request for the Court to 'annul the authorisation decision' was admissible.⁶⁶ On this point, the Court noted that Client Earth had misconstrued Article 266 of the TFEU.⁶⁷ The Court then concluded that the Court was not entitled to 'issue directions to the Commission' or to 'effect the revocation of the authorisation decision'⁶⁸ – and dismissed this Client Earth's request to annul the Authorisation decision as 'manifestly inadmissible'.⁶⁹ However, despite dismissing Client Earth's request for annulment of the initial decision actually granting Authorisation as inadmissible, it should be noted that the Court did nonetheless examine, in detail, many of Client Earth's arguments which related directly to the Commission's initial Decision to grant Authorisation to the three recycling companies in the first place. In other words, although the Court stated that Client Earth could not ask the Court to annul the initial Commission Decision which granted the three waste recycling companies REACH Authorisation,⁷⁰ the Court did, nonetheless, look at the underlying legal arguments regarding the legality of that decision in its

Judgment. Therefore, had the Court ultimately annulled the Commission Decision to reject the Client Earth request for an internal review, the core question would have been whether the Commission could tenably have upheld the initial Commission Decision granting REACH Authorisation to the three waste recycling companies at all. This is concerning to REACH applicants for REACH Authorisation. In essence it may give NGOs a 'backdoor' to legally challenge the legality of REACH Authorisations which have already been granted. Although NGOs could not, per se, directly legally challenge a Commission decision to grant Authorisation,⁷¹ the Client Earth case highlights the fact that NGOs may be able to bring actions before the Court via the Aarhus Regulation route, and then, if the case is successful, put pressure on the Commission to revoke the initial Commission Decision granting Authorisation pursuant to, amongst others, Article 266 of the TFEU. As a result, companies which are granted REACH Authorisation may, in the future, have to put as much effort into defending Authorisations from legal challenges brought by NGOs after they have been granted by the Commission, as they put into obtaining Authorisation in the first place.

b. Court Judgment – General Points

Having dismissed Client Earth's request to annul the Commission Decision which actually granted the applicants REACH Authorisation as inadmissible, the Court subsequently assessed Client Earth's main pleas regarding the Client Earth request for the Court to annul the Commission Decision rejecting Client Earth's request for an internal review under the Aarhus Regulation.⁷²

From the outset, it should be noted that the Court Judgment is lengthy and addresses various issues, too numerous to sufficiently detail in this commentary. The Court assessed, for example, issues such as the legal requirements which companies or individuals who make requests made pursuant to Article 10 of the Aarhus Access to Information Regulation⁷³ must comply with; the Commission's review of such requests;⁷⁴ and the admissibility of claims before the Court in this regard.⁷⁵ However, and of most importance for future applicants for REACH Authorisation, the Court assessed some of the most fundamental and important issues regarding applications for authorisation.

65 *ibid* Para 33.

66 Third head of claim, Para 21.

67 The Court noted that the Art 266 TFEU did not 'confer on the Court any power that would go beyond the jurisdiction expressly laid down in the Treaties' and noted that Article 266 of the TFEU addressed the obligation on the institution on whose act had been declared void to take necessary measures to comply with the annulling decision (Para 30). The Court stated that 'the Courts of the European Union are not entitled, when exercising judicial review of legality, to issue directions to the institutions' or to 'assume the role assigned to them'. (Para 30)

68 *ibid* Para 30.

69 *ibid* Para 31.

70 As Client Earth did not have legal standing.

71 As they are unlikely to have legal standing.

72 *ibid* Para 33.

73 *ibid* Para 57.

74 See, for example, *ibid* Para 58.

75 *ibid* Para 62.

c. Commission Required to Conduct its own Examination and has no Legal Power to 'Rectify' Deficient Applications for Authorisation

Similar to the Court's Judgment in the Swedish case, the Court re-iterated that the Commission was legally required to conduct an examination 'of its own motion' into the factual circumstances and other issues surrounding an application for authorisation, and could not limit its examination to the information and evidence provided by an applicant for authorisation.⁷⁶ Moreover, and again, in a similar way as the Court held in the Swedish case, the Court made it clear in the Client Earth case that the Commission had no legal ability to rectify or ignore deficiencies in an application for authorisation or chemical safety report⁷⁷ by, for example, granting REACH Authorisation but with shorter review periods. The Court held that the Commission was legally required to 'establish whether all the relevant facts and the technical and economic assessments relating to them support the conclusion that the conditions provided for [in Article 60 REACH] are...fulfilled.'⁷⁸ However, unlike in the Swedish case, although the Court recognized that the review period in the Client Earth case was 'a short one'⁷⁹, the Court concluded that there was 'no reason to consider that the Commission [had] attempted to remedy [deficiencies in the CSR] by setting a [short] review period'⁸⁰, as the deficiencies in the CSR merely meant that, in this case, the Article 60(2) route could not be used to obtain REACH Authorisation, and any remaining uncertainties surrounding the chemical safety report had ultimately been dispelled by the ECHA Committee opinions⁸¹.

d. Concept of 'Use' for REACH Authorisation

Perhaps of most importance to future applicants for REACH Authorisation, the Court clarified the concept of 'use' for REACH Authorisation. The concept of 'use' is of particular importance to applicants, as it not only dictates whether a particular company needs to obtain REACH Authorisation in the first place, it also dictates how widely 'use' should be defined and how many Authorisations, for different uses, a company should apply for and obtain.

In the Client Earth case, Client Earth argued that the 3 applicants had 'failed to define' the uses of the Annex XIV substance⁸² and that the Commission had also 'misinterpreted the concept of 'use' under Arti-

cle 56(1)(a) and 62(4)(c) REACH.⁸³ In essence, Client Earth argued that the 3 applicants had not identified or applied for any valid 'use of a substance' in accordance with the Title VII provisions, and/or that the applicants had defined the 'use' too broadly and/or in respect of the use or processing of a waste, not a substance.

According to Client Earth, 'use' should mean the 'technical function' of the substance⁸⁴ and involved active deployment or introduction of a substance 'in or into an industrial process.'⁸⁵ Client Earth argued that this corresponded to 'a concept of intentional use' of an Annex XIV substance.⁸⁶ In this case the application had requested REACH Authorisation for 'uses of recycled PVC containing DEHP.'⁸⁷ According to Client Earth, the application related to 'mere unintentional presence'⁸⁸ of an Annex XIV substance (DEHP) in waste and/or recycled plastic/PVC where DEHP was 'not used per se...[but] [was] merely present as a (largely unwanted) impurity...'⁸⁹ By failing to grant REACH Authorisation for the intentional use of the Annex XIV substance, and by granting instead REACH Authorisation for the 'recycling of materials' containing an Annex XIV substance⁹⁰, Client Earth contended that the Commission had manifestly erred in law⁹¹. Interestingly, Client Earth sought to make a clear distinction between, on the one hand, use of an Annex XIV substance contained in a mixture, and, on the other hand, use of a mixture itself. The Client Earth's position was, in essence,

76 See to that effect *ibid* Para 216.

77 See, for example, *ibid* Paras 100, 142, 140-151.

78 *ibid* Para 144.

79 *ibid* Para 146.

80 *ibid* Para 150.

81 *ibid* Paras 147-148.

82 *ibid* Para 35.

83 *ibid*; *ibid* Paras 181-187.

84 *ibid* Para 41.

85 *ibid* Paras 41 and 36.

86 *ibid* Para 36.

87 *ibid* Para 37.

88 *ibid*.

89 *ibid* Para 41.

90 Client Earth's contention was that the application was therefore essentially for the process of collecting, processing and selling of plastic waste containing the Annex XIV substance (DEHP) merely as an incidental ingredient, Para 37.

91 *ibid* Para 38.

that there was no ‘use’ (ie ‘active’⁹² use) of an individual Annex XIV substance in a mixture where the presence of that Annex XIV substance in the mixture was merely incidental or unintentional; and that any ‘use’ of the mixture could not be regarded as a ‘use’ of the unintended and incidental Annex XIV substance within it.⁹³ Client Earth also argued that the ability to conduct a proper analysis of alternatives and proper socio-economic assessment depended on the correct definition of the ‘use’ of an Annex XIV substance itself - as it was not possible to examine alternatives of the ‘use’ of the Annex XIV substance if the use was incorrectly defined.⁹⁴

In response to these arguments, the Court agreed with Client Earth that the concept of ‘use’ was important to the analysis of alternatives and socio-economic assessment as it ‘may have a bearing on the scope of the analysis of the different conditions set out in Article 60(2) and (4) [of REACH].’⁹⁵ However, despite the convincing nature of many of Client Earth’s arguments, the Court held that either Client Earth’s arguments regarding ‘use’ should be dismissed as inadmissible⁹⁶ or, in the alternative, some of the arguments were unfounded as the Commission had, in any event, not committed any error of law⁹⁷.

The Court noted that ‘use’ was defined in Article 3(24) REACH⁹⁸ and concluded that: (i) the concept of ‘use’ was ‘not limited to the active introduction of a substance ‘into an industrial process’ and (ii) that nothing in Article 3(24) indicated that for a substance to be ‘used’ it must be intentionally introduced into such a process.’⁹⁹

Importantly, the Court did not rebuff or dispute the notion that the ‘function’ of a substance is a critical factor in determining its ‘use’. On the contrary,

the Court acknowledged how important determining the ‘function’ of a substance was when assessing its ‘use’, and specifically assessed ‘function’ when considering Client Earth’s arguments on mixture and waste.

As regards mixtures, the Court stated that a substance should be considered as ‘used’ not merely when it has a specific function ‘within the context of a mixture’, but also where the ‘mixture as a whole’ is used and where, for example, the ‘entirety of the components perform a function only because of the use of the mixture as such.’¹⁰⁰ The Court concluded that a substance is therefore ‘used’ where a substance is contained within a mixture and ‘the characteristics of the substance have a certain function in that mixture’ and the function of the substance is, for example, only apparent when the mixture itself, as such, is used.¹⁰¹ In other words, whether or not a substance has a function within a mixture does not merely depend on whether the substance has a function within that mixture at the time the mixture is formulated or recovered. It also depends on whether the substance performs a function at the time the mixture itself is used.¹⁰² If using a mixture means, for example, that production of the virgin Annex XIV substance itself is phased-out and progressively replaced, this ‘use’ of a mixture does constitute a valid function and use of the Annex XIV substance itself.¹⁰³

As regards waste, the Court noted the distinction made in the Authorisation Decision between, on the one hand, recovered material (ie PVC recyclate) and, on the other hand, waste (ie PVC waste). On this point the Court again noted the ‘use’ of DEHP given its function, holding that ‘...when DEHP is present in recyclate, it has a precise ‘technical’ function: it reduces the amount of plasticizers that needs to be added in the production of soft PVC articles...’¹⁰⁴ Therefore, although the recycling companies did not intend to ‘use’ DEHP per se – and although the recovered materials merely contained DEHP as the DEHP was present in the initial feedstock material (ie the waste) which the recycling companies generally had no control over – the Court nonetheless concluded that as the presence of DEHP meant the amount of other plasticizers needed in the mixture supplied by the recycling companies was reduced, the DEHP did have a function and use. Given the Judgment, future applicants for authorisation may legitimately question whether an Annex XIV substance which is contained

92 *ibid* Para 41.

93 *ibid* Para 39.

94 *ibid* Para 40.

95 *ibid* Para 91.

96 *ibid* Para 62.

97 *ibid* Para 72.

98 *ibid* Para 63.

99 *ibid* Paras 64-69.

100 *ibid* Paras 69-70.

101 *ibid* Para 91.

102 *ibid* Para 70.

103 *ibid* Paras 91 and 43.

104 *ibid* Para 71; *ibid* Paras 71-72, 83-88.

in mixtures at such small quantities, has a ‘function’ (for example where it does not reduce the amount of other plasticizers needed in the mixture) – and can be regarded as being ‘used’ for the purposes of REACH Authorisation, and whether, therefore, REACH Authorisation is legally required. Also, if the performance characteristics of an Annex XIV substance deteriorates over time – future applicants for authorisation may also question whether, after a certain period of time, the substance has a ‘function’, is legally ‘used’ – and whether, therefore, REACH Authorisation is required.

e. Information on Worker Exposure and Risks

One of the arguments raised by Client Earth was that the Chemical Safety Report was deficient in that it did not adequately address the risks to workers exposed to DEHP as there was only minimal biomonitoring and air measurement data included in the CSR.¹⁰⁵ The ECHA RAC and SEAC committees had also noted this point; the RAC stating that ‘the information [in the CSR] was of ‘limited informative value.’¹⁰⁶ Client Earth argued that the ECHA RAC and/or Commission had erred in fact and in law, by concluding that the application was in conformity with Article 62 REACH (and included the necessary information), while at the same time acknowledging relevant data was missing from the application and, amongst other things, making Article 64(3) REACH requests for further information.¹⁰⁷

In response to this point, the Court made a distinction between ‘formal’ and ‘substantive’ requirements imposed on applicants, and which the Commission was legally required to verify, pursuant to the Title VII provisions.¹⁰⁸ The Court held that Article 60(7) REACH ‘put the Commission under a formal and procedural obligation’ to verify whether the application was in conformity with the requirements under Article 62(4) REACH ‘from a formal point of view.’¹⁰⁹ However, the Court also noted that neither Article 60(7) nor Article 62 REACH, concerned the ‘material conditions’¹¹⁰ that must be met for an authorisation to be granted from a ‘substantive’¹¹¹ perspective, and concluded that Articles 60(7) and 62 do not require the Commission to examine the substance of elements in an application for authorization.¹¹² As it was common ground that the application for authorisation in this case did contain all the elements in Article 62 and the formal conditions set out in Arti-

cle 60(7) – the Court dismissed this argument. As regards the substantive assessment, the Court held that Client Earth had not demonstrated an infringement of Article 60(4) REACH or an infringement of Articles 60(8) or 60(9)(e) REACH.¹¹³ The Court also stated that the requests mentioned in the second sentence of Article 64(3) REACH, do not concern the information referred to in Article 62 is complete or verifiable and therefore ‘does not concern a formal aspect of the application for authorization.’¹¹⁴

f. The Commission’s Risk Assessments Regarding REACH Authorisation

In the Client Earth case, Client Earth argued that the Commission had ignored the information on the endocrine-disrupting properties of DEHP which constituted a manifest error of law and assessment.¹¹⁵ On this point, and as mentioned above, the Court stated, as it did in the Swedish case,¹¹⁶ that the Commission was required to examine ‘of its own motion’ all relevant information available to it at the time of the authorisation decision, without being limited to the information provided in the application for authorisation. Similar to its Judgment in the Swedish case,¹¹⁷ the Court stated that the Commission’s role ‘was not that of an arbitrator whose competence only relates to the information and evidence provided by the applicant for authorization.’¹¹⁸ Nonetheless, the Court also stated that inclusion on the Candidate List, and inclusion on Annex XIV ‘constituted two different

¹⁰⁵ *ibid* Paras 95 and 135; *ibid* Paras 190-192.

¹⁰⁶ *ibid* Para 96; One of the issues related to the type and quality of data provided (eg need for measured exposure data) reflecting and sufficiently proving actual conditions of use in order to calculate an accurate and fair Risk Characterisation Ratio.

¹⁰⁷ *ibid* Paras 96-99 and 172-177

¹⁰⁸ *ibid* Paras 173.

¹⁰⁹ *ibid* Para 104.

¹¹⁰ *ibid* Para 106.

¹¹¹ *ibid* Para 108.

¹¹² *ibid* Para 109.

¹¹³ *ibid* Paras 138 and 150.

¹¹⁴ *ibid* Para 173.

¹¹⁵ *ibid* Para 205.

¹¹⁶ Case T-837/16 *Sweden v European Commission* [2019] ECLI:EU:T:2019:144, Para 64.

¹¹⁷ *ibid*.

¹¹⁸ Case T-108/17 *Client Earth v European Commission* [2019] ECLI:EU:T:2019:215, Para 216.

stages of the authorisation procedure.’¹¹⁹ Ultimately the Court concluded that ‘...only data relating to the intrinsic properties of a substance that have been included in Annex XIV [REACH] are relevant for the risk assessment referred to...in Article 60(4) [REACH]...’¹²⁰

V. Conclusions

The spring 2019 judgments contain important lessons for future applicants for REACH Authorisation. Applicants will have concerns regarding these judgments, in particular:

1. The fully separate and independent review of applications now required by the Commission – and whether the Commission will, for example, be inclined to reject applications for Authorisation even where ECHA believes an application should be granted.
2. The absence of any Commission guidance or insight into what the Commission (rather than ECHA) will require or insist applicants contain in applications for authorization.
3. The significant burden of proof that applicants may be required to satisfy in order to obtain a REACH Authorisation – including, perhaps, the eradication of any relevant uncertainty on the unavailability of alternatives in ECHA and the Commission’s minds.
4. The apparent onus on applicants to respond to any comments made during the public consultation or otherwise, rebutting any allegation or contention from a competitor, NGO or other person, that an alternative is, in their view, available to the applicant.
5. The fact that NGOs may, in the future, seek to use Aarhus requests for data (and any subsequent rejection by the Commission of such requests) as a means of starting a legal procedure which could, ultimately, overturn Commission decisions which have already granted a company REACH Authorization.

119 *ibid* Para 222.

120 *ibid* Paras 220-221.