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Advocate General endorses reliability and impartiality of EU rules on plant protection products

On 12 March 2019, the Advocate General ("AG") Sharpston delivered her non-binding Opinion to the European Court of Justice ("ECJ") in a preliminary reference case referred to it by France questioning the validity of the risk assessment system set up by Regulation 1107/2009 ("PPP Regulation"). The AG opinions in favour of upholding the validity of the PPP Regulation considering that the risk assessment under that regulation is adequately comprehensive, independent and transparent (C-616/17, Blaise and Others).

WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS

- French courts have referred two cases to the ECJ asking it to rule on the validity of the PPP Regulation. Both cases are still pending, but the AG Sharpston has delivered a non-binding Opinion in the first case dismissing the defendants' claim that the PPP Regulation would be flawed.
- The AG examines the relevant provisions of the PPP Regulation and its related secondary legislation to conclude that the existing system for risk assessment of active substances and plant protection products is adequate. It ensures a comprehensive and independent assessment of the complete data dossier submitted by the industry applicant in compliance with objective quality requirements. The PPP Regulation further guarantees adequate transparency bearing in mind that there is no absolute public right to access the entire dossier or to conduct a counter risk assessment.

Background

This case originates in France where a number of environmental activists are facing criminal charges for damaging containers of herbicides containing glyphosate (Roundup) in shops. In their defence, they argue in essence that the overall system of plant protection product regulation at EU level, namely the PPP Regulation, is defective and therefore unlawful using the case of glyphosate as an example. Against a background of disputed science on glyphosate and noting that the PPP Regulation is based on the precautionary principle, the French Criminal Court of Foix decided to put the question of the validity of the PPP Regulation before the ECJ.

The AG Opinion

The AG emphasises first that this case is not about the specific case of glyphosate, but that the ECJ is asked to rule whether the overall system of the PPP Regulation affecting all plant protection products is flawed in such a manner as to render that regulation invalid. The AG notes that the European Parliament report formulating certain recommendations to improve the PPP Regulation does not imply that the current system is flawed as a whole. In addition, the ECJ is asked to consider whether the PPP Regulation duly respects the precautionary principle, specifically whether the risk assessment under...
that regulation is adequately comprehensive, independent and transparent.

Contrary to the defendants' claim, the AG concludes - having considered the relevant provisions of the PPP Regulation - that the current system of risk assessment does take into account cumulative and synergistic effects (i.e. exposure to the combination of products containing the same or different active substances). In addition, the AG points out that the system allows for "safety nets", namely precautionary measures, to remedy possible errors in individual cases where necessary (e.g. restrictions may be imposed following the approval of a substance).

The AG further dismisses in their entirety the assumptions that the risk assessment would be not be impartial or transparent because the industry applicant could submit a biased data set for assessment which is not 'counter-analysed' independently and moreover benefit from "industry-friendly" confidentiality rules preventing third party scrutiny. The AG underlines, to the contrary, that the applicant is required to submit a complete dossier which must comply with the standard and the objective quality requirements set by the PPP Regulation. These, according to the AG, "preclude an industry applicant from itself conducting the necessary studies against its own (biased) protocols and (partial) standards and choosing which data it prefers to submit in its dossier". Further, the PPP Regulation requires all risk assessments, both at EU and national level, to involve a "systemic independent analysis" of the material submitted by an industry applicant.

The AG also rejects the claim that the current confidentiality rules, and in particular Article 63 PPP Regulation, would unduly prevent third party scrutiny and would imply that the overall system is insufficiently transparent or independent. The AG stresses that there is "no absolute public right to access all of the data in an industry applicant's dossier" and that "a third party does not have an absolute right to conduct a counter risk assessment by reference to the industry applicant's dossier of raw data". In any event, the AG notes, the PPP Regulation already offers third parties certain mechanisms in this regard (e.g. publication of the summary dossier and draft assessment report).

A judgment in this case is still pending and will determine also the outcome of the similar preliminary ruling request currently pending before the ECJ in C-115/18, Carluer and Others.

EU Court annuls EFSA refusal to disclose glyphosate studies

In two judgments issued on 7 March 2019, the EU General Court ("GC") holds that the European Food Safety Agency ("EFSA") was wrong to refuse public access to toxicity and carcinogenicity studies on the active substance glyphosate. In particular, the GC takes the view that the requested studies should be regarded as information relating to emissions into the environment whose disclosure, under the Aarhus transparency rules, cannot be refused to protect legitimate commercial interests, including intellectual property rights (T-716/14, Anthony C. Tweedale -v- EFSA and T-329/17, Hautala and Others -v- EFSA). These rulings are difficult to reconcile with the GC's own judgment of last year upholding the EU Commission's decision to treat glyphosate substance data as confidential and deny disclosure (see the January 2019 edition of our newsletter).

WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS

- The Aarhus Regulation (1367/2006) regulates public access to environmental information held by EU institutions, including the EU Commission and EFSA. Access may, as a rule, be denied to protect commercial interests, including intellectual property rights, unless an overriding public interest in disclosure exists. An overriding public interest is deemed to exist for "information relating to emissions into the environment" (Article 6(1) Aarhus Regulation, the "Aarhus Emissions rule").
- The GC ruled last year that an EU substance approval dossier - such as that
of glyphosate - contains no information relating to environmental emissions. As a result, public disclosure of active substance data can be legitimately refused when necessary to protect the confidentiality of commercial and industrial information. The GC concluded that the EU Commission was right to reject environmental NGOs' request for access to parts of the glyphosate approval dossier revealing the chemical composition of the substance and its manufacturing process.

- In its most recent judgments, however, the GC departs from last year's ruling by considering that certain toxicity and carcinogenicity studies in the EU renewal dossier of glyphosate must be classified as "information relating to environmental emissions". It was therefore not possible for EFSA to deny disclosure to protect commercial interests. The two judgments are open for appeal before the EU Court of Justice ("ECJ").

Background

Access requested to certain parts of two toxicity studies and twelve carcinogenicity studies submitted for the renewal of the EU approval of glyphosate. All requested studies were carried out in a laboratory involving the administration of high doses of glyphosate to test animals.

EFSA refused access to the requested studies invoking the need to protect the data owners' commercial interests under Article 4(2) Regulation 1049/2001 and the sector-specific confidentiality rule of Article 63(2) PPPR. It did not consider the studies to contain "information relating to environmental emissions". EFSA further noted that the public already has sufficient access to the scientific information relating to the safety of glyphosate by the publication of the public version of the draft "renewal assessment report" ("RAR") prepared by Germany and available on EFSA's website.

The Court judgments

Following the 2016 landmark ruling of the ECJ in C-673/13 P, Commission -v- Stichting Greenpeace Nederland and PAN Europe, the GC examined for the first time last year how the Aarhus Emissions rule must be applied concretely to regulatory data submitted by companies to obtain the EU approval of glyphosate. In its 21 November 2018 judgment, the GC agreed with the EU Commission that the glyphosate approval dossier does not contain any information relating to environmental emissions. Public access to such information may therefore be denied where there is a need to protect confidential business information (e.g. details on the manufacturing process) (T-545/11 RENV, Stichting Greenpeace Nederland and PAN Europe -v- Commission).

Based on the dual nature of the EU regime whereby a substance (such as glyphosate) is approved at EU level and plant protection products containing the approved substance subsequently require an assessment and authorisation in each Member State, the GC concluded last year that the EU assessment does not involve information on actual or foreseeable emissions into the environment, since the substance is "not intended to be released into the environment as such, but may be released only once integrated in a plant protection product subject to authorisation" (see the January 2019 edition of our newsletter).

The two recent GC rulings (delivered by a different chamber of judges) however take a radically different approach. Indeed, the GC concludes that the requested toxicity and carcinogenicity studies, that form part of the renewal dossier of glyphosate, qualify as information relating to environmental emissions. Therefore, EFSA should have presumed an overriding public interest in disclosing the studies.

In particular, contrary to what it held itself in its last year's ruling, the GC first takes the view that an active substance is intended to be released into the environment and that glyphosate emissions into the environment are a reality since formulations containing glyphosate are authorised and actually used in the EU. Glyphosate emissions are therefore to be regarded as 'actual' emissions. Second, the GC concludes that the requested studies contain information on such actual glyphosate emissions, because their "purpose" was to study whether such emissions may have harmful effects on human health (and therefore the environment).

The two rulings are difficult to reconcile with the GC's earlier judgment which also concerned the disclosure of information contained in the approval dossier of glyphosate. An appeal against the two judgments can be brought within two months from notification.
EU Court sides with Sweden and annuls REACH authorisation for lead chromates

On 7 March 2019, the General Court ("GC") for the first time annulled a REACH authorisation allowing certain uses of a Substance of Very High Concern. Sweden brought the action before the GC seeking the annulment of the EU Commission's decision to authorise certain uses of lead sulfochromate yellow and lead chromate molybdate sulphate red. (T-837/16, Sweden -v- Commission). The judgment may be appealed before the EU Court of Justice ("ECJ").

WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS

- The GC for the first time annulled an EU Commission authorisation decision under REACH. In 2016, the EU Commission conditionally authorised several uses of lead chromates under the called "socio-economic" procedure of Article 60(4) REACH.

- Following an action for annulment brought by Sweden against the authorisation decision, the GC concluded that the EU Commission infringed REACH by authorising the lead chromates without having duly examined and established the unavailability of suitable alternatives. In essence, the GC upheld Sweden's plea that the EU Commission infringed REACH by authorising the lead chromates without having duly examined and established the unavailability of suitable alternatives. Given the conflicting evidence available at the time, the EU Commission should have examined this condition in even greater detail and could not simply rely on the scientific assessment performed by the competent European Chemicals Agency ("ECHA") committees.

The Court judgment

The GC annulled the authorisation in its entirety. In essence, the GC upheld Sweden's plea that the EU Commission infringed REACH by authorising the lead chromates without having duly examined and established the unavailability of suitable alternatives. As a result, the EU Commission was wrong to grant an authorisation, even a conditional one. The GC stresses that a conditional authorisation cannot be used to remedy shortcomings and defects in the EU Commission's statutory duty under Article 60(4) REACH to examine the absence of alternatives.

Article 60(4) REACH provides that an authorisation may only be granted if it is demonstrated, with the assistance of the ECHA committees, that the socio-economic benefits outweigh the risks to human health or the environment from the use of the substance and that no suitable alternative substances or technologies exist. The GC stresses that the economic" procedure of Article 60(4) REACH. The authorisation was made conditional on a shorter review period due to difficulties in fully establishing the unavailability of technically feasible alternatives for all uses. The authorisation was also made subject to reporting requirements for the authorisation holder and downstream users to report respectively to the EU Commission and ECHA on the adequacy and availability of alternatives.

The EU Commission based its decision on ECHA scientific opinions indicating the absence of suitable alternatives. The opinions however reveal that the applicant had not provided an analysis of the alternatives for all uses and that the public consultation on the availability of lead-free alternatives had given rise to conflicting statements.

Sweden voted against the draft authorisation decision and, following its adoption, brought a legal action before the GC seeking the annulment of the authorisation. Denmark, Finland and the European Parliament intervened before the GC in support of Sweden.

Background

Lead sulfochromate yellow and lead chromate molybdate sulphate red are used in varnishes and paints for metal surfaces or for road marking. Due to their carcinogenic and reproductive toxic properties, the pigments were included in the list of Substances of Very High Concern subject to REACH authorisation (Annex XIV).

In 2016, the EU Commission authorised several uses of lead chromates under the called "socio-economic" procedure of Article 60(4) REACH. The authorisation was made conditional on a shorter review period due to difficulties in fully establishing the unavailability of technically feasible alternatives for all uses. The authorisation was also made subject to reporting requirements for the authorisation holder and downstream users to report respectively to the EU Commission and ECHA on the adequacy and availability of alternatives.

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The Court judgment

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burden of proof is on the applicant to demonstrate that no alternative solution is available.

The EU Commission has the sole responsibility to verify that the conditions of Article 60(4) REACH are met and, where necessary, to verify and complete ECHA's scientific assessment. An authorisation may be granted only provided that the EU Commission has duly verified all available information to determine that the applicant had satisfied this burden of proof. The absence of such detailed examination means that no authorisation should have been granted.

In the present case, the EU Commission's examination of the condition on the unavailability of suitable alternatives had not been duly completed at the time of the adoption of the authorisation decision. Uncertainty remained as to the unavailability of alternatives which meant that the applicant did not satisfy the burden of proof and an authorisation - even conditional - should not have been granted.

The EU Commission may in principle proceed with an authorisation based on ECHA's scientific opinions, without additional scientific examination. However, where there is conflicting evidence, the EU Commission's duty of care requires it to examine in even greater detail the condition of unavailability of alternatives. A further detailed examination was required in this case before granting an authorisation. The GC considers the plea of proportionality irrelevant where the conditions for the grant of an authorisation are not met.

Provided that no appeal is introduced against the judgment within two months from its notification, the authorisation will disappear from the EU's legal order with immediate effect as if it had never existed. The GC also rejected the EU Commission's request, on grounds of legal certainty, to maintain the effects of the annulled decision until a new assessment of the authorisation application has been made. The EU Commission and ECHA have indicated that they are analysing the judgment, presumably in view of a possible appeal.

### EU highest Court clarifies 'carve-out' option for generic human medicines

In its judgment of 14 February 2019, the EU Court of Justice ("ECJ") clarifies the 'carve-out' rule of Article 11 of the Human Medicines Directive (2001/83) which allows generic market entry despite several indications or dosage forms of the reference product still being patented (C-423/17, Warner-Lambert Company). In doing so, the ECJ follows the pragmatic approach proposed by the Advocate General which we discussed in detail in the November 2018 edition of our newsletter.

**WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS**

- Where several indications or dosage forms of the reference product still enjoy patent protection, EU law nevertheless allows the authorisation of generic medicines for the unpatented indications and dosage forms (after the data exclusivity period for the reference product has expired). The rationale is not to delay generic market entry until expiry of all patents linked to the reference product.

- EU rules governing the marketing of human medicines are based on the principle that the marketing authorisation of a generic medicinal product and that of a reference product must tally. The 'carve-out' rule of Article 11 of the Human Medicines Directive (2001/83) forms an exception to this principle.

- The 'carve-out' rule allows generic manufacturers to exclude the patented indications or dosage forms from the summary of the product characteristics ("SmPC") when applying for the authorisation of a generic medicine. The ECJ confirms that, by doing so, the
generic applicant automatically limits the scope of its generic marketing authorisation application which the competent authority is bound to accept (no discretion).

The ECJ’s ruling begins by underlining several fundamental principles governing the marketing of human medicines in the EU: first, the package leaflet and the SmPC form part of the marketing authorisation, second, the medicinal product placed on the market must fulfil the conditions of the marketing authorisation, which must be reflected in the SmPC and, third, the marketing authorisation holder may not amend the package leaflet or the SmPC without notifying the competent authority in order to obtain its approval.

In respect of generic medicines, the ECJ notes that EU law requires, in principle, the application for marketing authorisation of a generic medicinal product to be limited to the indications covered by the marketing authorisation of the reference product. As a result, the SmPC accompanying the generic application cannot cover indications or dosage forms which are not consistent with those covered by the wording of the marketing authorisation of the reference product. In other words, the marketing authorisation and SmPC of the reference product and that of the generic product should tally.

However, the 'carve-out' rule of Article 11 of the Human Medicines Directive (2001/83) exceptionally allows a generic applicant to derogate from this principle. A generic applicant is given the possibility to reduce the scope of its application to exclude those indications or dosage forms still covered by patent law. The rationale is not to delay generic market entry until expiry of all patents linked to the reference product.

According to the ECJ, where the generic applicant leaves out certain indications or dosage forms from the SmPC, it makes use of the carve out limiting the scope of the application. The competent national authority does not have any discretion in that respect. Where the marketing authorisation for the generic product has already been granted and the generic company communicates an SmPC to the competent authority from which certain indications have been removed, this qualifies as a minor type IB variation requiring the authority to amend the marketing authorisation to bring it in line with the changed SmPC.

The ECJ further notes that the marketing authorisation holder should request a type II variation when, upon expiry of the protection period by a patent of an indication covered by the marketing authorisation of the reference medicinal product, the holder wishes to add that indication to those already authorised for the generic product.

Board of Appeal annuls ECHA decision for breach of right to be heard

In its decision of 29 January 2019 (A-0005-2017), the ECHA Board of Appeal (“BOA”) annuls a decision of the European Chemicals Agency (“ECHA”) announcing its intention to revoke the REACH registration of a substance on account of a violation of the joint submission requirement. The BOA finds that ECHA failed to follow its own procedures and acted in violation of the registrant’s procedural rights.

WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS

- A decision whereby ECHA finds that a registrant has failed to comply with the joint submission requirement must be based on, and adopted in accordance with, the specific procedure set out in Article 20 or Article 41 REACH. Such a decision is appealable to the ECHA BOA.
- A registrant must be given the opportunity, as appropriate, to justify why it considers its substance to be different from a substance previously registered.
under REACH. ECHA’s failure to provide such an opportunity, before adopting a decision, constitutes a violation of the registrant’s procedural rights which may lead to the annulment of ECHA’s decision where the procedural defect may have altered the outcome of the procedure.

**Background**

In May 2013, Thor GmbH (the “Appellant”) registered a substance carrying the same name and EC identifier as a substance previously registered by two subsidiaries of the Solvay group ("Solvay"). Subsequently, in application of the principle 'one substance, one registration', Solvay lodged a joint submission and invited the Appellant to join, in accordance with Implementing Regulation 2016/9 which entered into force in March 2015. This regulation expressly requires registrants of the same substance to submit data jointly. Following discussions on the identity of the registered substance, however, the Appellant decided not to join the Solvay submission.

On 13 February 2017, ECHA issued a communication informing all registrants, i.e. the Appellant and Solvay, that, as separate registrations had been submitted for the same substance, ECHA considered that the joint submission requirement had been breached and that it intended to revoke the existing substance registration (the "Decision").

The Appellant challenged the Decision before the BOA, alleging a breach of its right to be heard, the principle of good governance and the procedural requirements set out in Articles 41, 50 and 51 REACH insofar as ECHA had failed to give it an opportunity to explain why it considered its own substance to be different from the substance registered by Solvay.

**BOA ruling**

The BOA upholds the appeal and annuls the Decision.

As the Decision has in fact the same content and legal effects as a decision rejecting a substance registration, following a completeness check under Article 20(2) REACH, the BOA confirms that such an ECHA communication to registrations is appealable before it.

In essence, the BOA concludes that ECHA failed to comply with Article 20 or Article 41 REACH in adopting the Decision. As a result, the Appellant was stripped from the opportunity to comment on the draft Decision and in particular to justify why it had decided not to become part of the joint submission. The BOA thus finds that ECHA acted in breach of the Appellant’s procedural rights, in particular the right to be heard and the right to an appeal.

The BOA then considers that this procedural defect could have altered the outcome of the procedure and therefore should lead to the annulement of the Decision. The BOA took account in this context of the fact that the Appellant had registered a substance of variable chemical composition (UVCB substance), whereas Solvay had registered a multi-constituent substance. In addition, the Appellant had consistently disputed the substance sameness. Taking this into consideration, the BOA concludes that the sameness of the substances was uncertain and that ECHA should have resolved this uncertainty, and considered the Appellant’s arguments, before taking a decision on the matter.

**No maladministration in EU Commission's process for updating chemical testing methods**

On 30 January 2019, the European Ombudsman (“Ombudsman”) adopts a decision on how the EU Commission deals with updates of the Test Method Regulation (440/2008) (“TMR”). The TMR defines the approved methods for chemical testing under REACH and must be updated by the EU Commission with potential alternative non-animal test methods. The decision finds no maladministration associated with the EU Commission’s process for updating the TMR, but does identify certain areas of improvement.
**Background**

The EU Commission is required to regularly review approved methods for chemical testing under REACH in order to minimise animal testing as far as possible. Where alternative non-animal test methods are identified, the EU Commission must consult the relevant stakeholders and, if appropriate, make a proposal to update the TMR "as soon as possible".

In practice, the EU Commission systematically consults the OECD where guidelines on chemical testing are prepared. Once these guidelines are adopted, the EU Commission submits an update proposal to Member States under the 'regulatory procedure with scrutiny' (which involves the REACH Committee issuing an opinion on the proposal and the European Parliament and Council having the right to veto). In case of "undue delay" within the OECD, the EU Commission proceeds with the TMR update.

Following a complaint by a UK animal welfare organisation, the Ombudsman opened an inquiry into the complainant's concerns that (i) the EU Commission should not consult the OECD on possible TMR updates, and (ii) the EU Commission takes too long to update the TMR.

**Decision**

The Ombudsman recalls that, while the EU has committed to minimise animal testing and conduct such testing only as a last resort, this duty must be interpreted in the light of the precautionary principle. Accordingly, the EU Commission may involve the OECD, since this scientific verification procedure contributes to the legitimate objective of protecting human health and the environment.

While the Ombudsman recognises that the whole process for updating the TMR may accordingly be lengthy in certain cases, nothing indicates that the process would be inherently flawed or involve unnecessary delays. As a result, no maladministration was found on the part of the EU Commission. Nonetheless, the Ombudsman suggests that the EU Commission should intensify its efforts to simplify and speed up the process and, in particular, should ensure, where feasible, that it carries out the other steps necessary for updating the TMR in parallel with the OECD's verification process.

**New actions**

**EU approval of plant protection substances**

On 8 March 2019, the European Ombudsman opened a new inquiry into the EU Commission’s approval process of active substances for plant protection use following two complaints from Pesticide Action Network Europe. In a letter addressed to the Commission President Juncker, the Ombudsman invites the EU Commission, as a first step in the inquiry, to agree to a meeting and provide documents by 30 April 2019, in relation to the active substances flazasulfuron, isofetamid, picolinafen, benzovindiflupyr and epoxiconazole (case 1570/2018/JN).

**Aarhus internal review - Concept of 'measure of individual scope'**

Meliflora, a German beekeeping association, lodged an appeal against the EU General Court judgment of 27 September 2018 in so far as it ruled that the extension of the approval of glyphosate is not an administrative act amenable to internal review under Article 10 of the Aarhus Regulation (T-12/17, Meliflora eV -
v- Commission). Mellifera contests this interpretation and argues that the extension is a measure of individual scope (C-784/18 P, Mellifera eV -v- Commission, OJ of 11 February 2019).

An action has been brought before the EU General Court against the European Investment Bank ("EIB")'s refusal to conduct an internal review of its decision to fund a biomass plant in Galicia, Spain. The applicant claims that the EIB erroneously applied Article 10 of the Aarhus Regulation and, in particular, the status of ClientEarth as a non-governmental organisation, the concept of 'administrative act', the definition of 'measure of individual scope', and the limits of environmental law (T-9/19, ClientEarth -v- EIB, OJ of 25 February 2019).

**Approval of biocidal substance empenthrin**

A new action has been brought before the EU General Court challenging the EU Commission's refusal to approve substance empenthrin for use in biocidal products of product-type 18 (T-734/18, Sumitomo Chemical and Tenka Best -v- Commission, OJ of 25 February 2019).

**Renewal of plant protection substance thiram**

A new action has been brought before the EU General Court against the EU Commission's decision not to renew the approval of thiram and to prohibit the use and sale of seeds treated with plant protection products containing thiram. A separate application for interim relief has also been introduced before the General Court (T-740/18, Taminco and Arysta LifeScience Great Britain -v- Commission, OJ of 25 February 2019).

**Renewal of plant protection substances - Public access to EFSA documents**

An action has been brought before the EU General Court against EFSA's assessment of the applicant's confidentiality claims in the context of an application for renewal of the approval of the active substance ethoprophos. A parallel request for the immediate suspension by the Court of the implementation of EFSA's decision is pending (T-720/18, AMVAC Netherlands -v- EFSA, OJ of 18 February 2019).

**CONTACTS**

For further information on any of the issues raised in this newsletter, please speak to your usual contact at Ashurst or:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Telephone</th>
<th>Mobile</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denis Waelbroeck</td>
<td>Partner</td>
<td>+32 2 641 9963</td>
<td>+32 475 45 69 43</td>
<td><a href="mailto:denis.waelbroeck@ashurst.com">denis.waelbroeck@ashurst.com</a></td>
</tr>
<tr>
<td>Donald Slater</td>
<td>Counsel</td>
<td>+32 2 626 1916</td>
<td>+32 473 132 473</td>
<td><a href="mailto:donald.slater@ashurst.com">donald.slater@ashurst.com</a></td>
</tr>
<tr>
<td>Jessica Bracker</td>
<td>Associate</td>
<td>+32 2 641 9937</td>
<td>+32 478 900 577</td>
<td><a href="mailto:jessica.bracker@ashurst.com">jessica.bracker@ashurst.com</a></td>
</tr>
<tr>
<td>Irene Antypas</td>
<td>Counsel</td>
<td>+32 2 641 9966</td>
<td>+32 471 129 991</td>
<td><a href="mailto:irene.antypas@ashurst.com">irene.antypas@ashurst.com</a></td>
</tr>
<tr>
<td>Antoine Accarain</td>
<td>Associate</td>
<td>+32 2 641 9938</td>
<td>+32 476 782 085</td>
<td><a href="mailto:antoine.accarain@ashurst.com">antoine.accarain@ashurst.com</a></td>
</tr>
<tr>
<td>Jessica Bracker</td>
<td>Associate</td>
<td>+32 2 641 9937</td>
<td>+32 478 900 577</td>
<td><a href="mailto:jessica.bracker@ashurst.com">jessica.bracker@ashurst.com</a></td>
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