



Legal Cases Update

Croplife Europe,
Sustainable solutions to protect crops

Darren Abrahams



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dabrahams@steptoe.com

*"exceptional expertise on EU regulations on chemicals...and a great ability to understand the complexity of businesses."
Chambers & Partners Europe, 2019*

- **English barrister, *Avocat* at the Brussels Bar**, partner resident in Brussels.
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market**.
- He focuses on **defence of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.
- Chambers & Partners **Europe-wide Regulatory (2020): Agro/Food and Environment Legal Rankings: top tier practitioner in both, and Steptoe listed as a band 1 firm.**

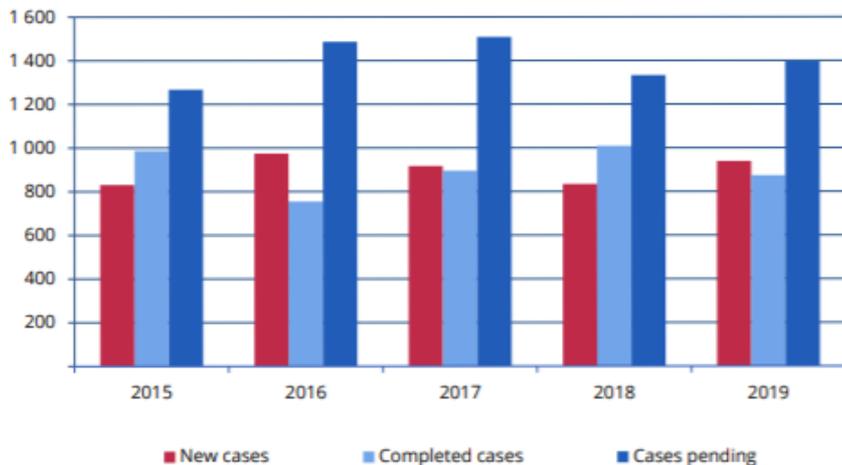
Topics

- Key stats from the CJEU
- Interim Relief cases
- Main actions:
 - Aarhus
 - Standing
 - Emergency measures
 - Renewal procedures

Key CJEU Statistics 2019

I. General activity of the General Court —

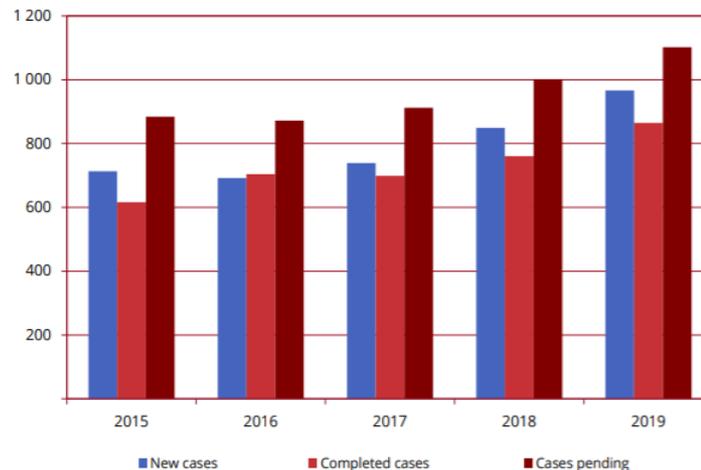
New cases, completed cases, cases pending (2015-2019) ^{1 2}



| | 2015 | 2016 | 2017 | 2018 | 2019 |
|-----------------|-------|-------|-------|-------|-------|
| New cases | 831 | 974 | 917 | 834 | 939 |
| Completed cases | 987 | 755 | 895 | 1 009 | 874 |
| Cases pending | 1 267 | 1 486 | 1 508 | 1 333 | 1 398 |

I. General activity of the Court of Justice —

New cases, completed cases, cases pending (2015-2019)



| | 2015 | 2016 | 2017 | 2018 | 2019 |
|-----------------|------|------|------|-------|-------|
| New cases | 713 | 692 | 739 | 849 | 966 |
| Completed cases | 616 | 704 | 699 | 760 | 865 |
| Cases pending | 884 | 872 | 912 | 1 001 | 1 102 |

Crop Protection Solution Cases in 2020

| Subject Area | 2020 | | | | | | | Ref. for Preliminary Ruling | Direct Action | Applications for Interim measures | Appeals of Direct Actions | Appeals on Interim measures | |
|--------------|-----------------|---|--|--|--|--|--|-----------------------------|---------------|-----------------------------------|---------------------------|-----------------------------|--|
| PPP | 3-Dec-20 | C-352/19 P - Région de Bruxelles-Capitale v Commission | | | | | | | | | | 1 | |
| PPP | 28-Oct-20 | C-313/19 P - Associazione GranoSalus v Commission | | | | | | | | | | 1 | |
| PPP | 8-Oct-20 | C-514/19 - Union des industries de la protection des plantes | | | | | | 1 | | | | | |
| PPP | 3-Sep-20 | C-784/18 P - Mellifera v Commission | | | | | | | | | | 1 | |
| PPP | 12-Aug-20 | T-162/20 R - UPL Europe and Indofil Industries (Netherlands) v EFSA | | | | | | | | | 1 | | |
| PPP | 8-Jun-20 | T-77/20 R I - Ascenza Agro and Industrias Afrasa v Commission | | | | | | | | | 1 | | |
| PPP | 8-Jun-20 | T-77/20 R II - Ascenza Agro and Industrias Afrasa v Commission | | | | | | | | | 1 | | |
| PPP | 28-May-20 | T-574/18 - Agrochem-Maks v Commission | | | | | | | | 1 | | | |
| PPP | 11-Mar-20 | T-612/19 R - UPL Europe and Aceto Agricultural Chemicals v Commission | | | | | | | | | 1 | | |
| | | | | | | | | | | | | | |
| | * Totals | | | | | | | 1 | 1 | 4 | 3 | 0 | |

*(Excludes withdrawn cases)

Interim measures

No automatic interim relief before CJEU (because presumption of lawfulness).

Interim measures hurdle is very high and historic success rate low (though a few notable successes on PPPs). Three cumulative tests:

- ***prima facie* case**: basically sound or doomed to fail?
 - **urgency**: serious and irreparable damage (not purely financial)
 - **balance of interests**: must outweigh the *status quo*
- Source: TFEU and Rules of Procedure
- Source: Caselaw

Analysis is very fact pattern specific and the judge exercises a wide discretion.

Confidential economic information redacted from Orders.

Interim measures: T-612/19 R (non-renewal decision on AS)

| Claim | Court Rebuttal (urgency only) |
|--|--|
| Risk of bankruptcy and loss of turnover | <ul style="list-style-type: none"> • Purely financial loss, <10% of turnover companies (old parent and its group) not threatening existence before judgment • Even where 2/3 of turnover loss: in a highly regulated sector requiring major investment, the risk of public health measures is borne by companies. • No evidence on new parent (taking over from Chapter 11 former parent) or its group |
| Late indication of non-re-approval - no sense in diversifying from only product. | <ul style="list-style-type: none"> • Risk on non-approval inherent in regulatory system • High probability known from Comm proposal (17 months before final decision) • No evidence that new parent company was unable to invest in diversification (only on old) |
| No skills to adapt technically | <ul style="list-style-type: none"> • No argument to support claim |
| Uncertainty from old parent's bankruptcy & Brexit | <ul style="list-style-type: none"> • No financial evidence • New parent made old parent's troubles irrelevant • Withdrawal agreement transitional period sufficient for group to adopt a commercial strategy |
| Would be unable to return to the product market because of alternative competitors | <ul style="list-style-type: none"> • Not a producer or distributor of products (just authorisation holder and responsible for reg. dossier) so not clear what market share might be lost |
| New approval would take 5 years and large investment | <ul style="list-style-type: none"> • No supporting financial info. on new parent. • Main case would be decided well before the 5 year window |
| Reputational harm | <ul style="list-style-type: none"> • If any – already occurred when non-renewal adopted (interim relief pending main decision would not restore this); extensive publicity already • Non-renewal actually viewed as a normal part of the procedure |

Interim measures: T-77/20 R I & II (non-renewal decision on AS)

| Claim | Court Rebuttal (urgency only) |
|---|--|
| <p>Despite absence of serious and irreparable damage - a situation of urgency arising from unique circumstances</p> | <ul style="list-style-type: none"> • Extraordinary circumstances do not establish urgency. They <i>might</i> establish the balance of interests in favour of interim measures |
| <ul style="list-style-type: none"> • Covid-19 | <ul style="list-style-type: none"> • No evidence it actually affected company value • Measures taken in Spain and Portugal were designed to ensure marketing of essential agri. Products during Covid so significant impact unlikely |
| <ul style="list-style-type: none"> • Loss of sales & market share etc. | <ul style="list-style-type: none"> • Purely financial loss (see thresholds in previous case) • Applicants did not claim to be in a situation liable to imperil very existence. • <i>“Economic operators are increasingly confronted with a regulatory environment hostile to traditional chemicals because of the Commission’s stated objective of significantly reducing the use and risk of chemical pesticides”</i> so evidence of measures taken to avoid impacts needed even if above 10% threshold • Absence of specific and precise information, supported by detailed, certified documentary evidence (because commercial choices would have to be made in disadvantageous timescale) – but in any event impact v. turnover too low. • Even if unquantifiable, harm must be serious and irreparable • For the re-seller, it is not clear what change in production it would have to take • Need to show loss of market share and that regaining significant portion would be impossible for structural/legal reasons • No evidence that financial compensation would be insufficient |

Interim measures: T-162/20 R (publication of EFSA conclusions)

| Claim | Court Rebuttal (<i>prima facie</i> case only) |
|---|--|
| <p>Merits of the EFSA decision</p> <ul style="list-style-type: none">• Incomplete/inaccurate info• Misinterpretation | <ul style="list-style-type: none">• Scientific assessment (non-legally binding) may be incorrect without being confidential• Backdoor challenge to EFSA substantive assessment (not the internal review decision on disclosure)• Non-disclosure is the exception under Art. 63 PPPR and Renewal Reg. and no arguments to establish <i>prima facie</i> case• No obligation for EFSA to provide reasons to justify the <i>publication</i> of its conclusions• Disclosure of false information does not necessarily cause commercial interests• Lack of verifiable and convincing evidence of confidentiality of disclosed information |
| <p>PAD Regulation exemption on undermining decision making process</p> | <ul style="list-style-type: none">• Irrelevant to Art. 63 PPPR & GFL |

Glyphosate Cases: Aarhus

C-784/18 P: on 2016 extension of approval period for glyphosate

- Request for Art. 10 “[internal review](#)” made under Aarhus Implementing Reg. rejected because the **Implementing Reg. was not an “administrative act** under environmental law” of “individual scope” (as required) but a measure of general scope allowing. Approvals are about a substance use rather than an individual permit and lead to other independent decisions on PPP authorisations.
- **5 weeks later, Comm proposal to amend** scope in [COM\(2020\) 642 final](#) to include measures of “general scope”. (Draft ENVI Comm report issued in February 2021.)

Glyphosate Cases: Standing

C-313/19 P: on 2017 renewed approval of glyphosate

- National association of wheat producers and consumers etc. held not have an interest in annulment of the Implementing Regulation – a regulatory act.
- **SO, only direct concern had to be shown (i.e., legal situation directly affected and no discretion to addressee).**
- **BUT was not *automatically* affected because there could be a subsequent PPP authorization with national mitigation measures and even refusal. Only at stage 2 would there be direct effects (not *automatically* at stage 1) so lower standing requirement for regulatory acts not met. Future possible PPP authorisations NOT implementing measures.**

C-352/19 P: on 2017 renewed approval of glyphosate

- Brussels Region annulment action rejected on standing – direct concern test. NO automatic effect of AS approval on PPP authorisations (contrary to no-approvals).
- Brussels Region was only “involved” in drawing up federal regulations on product standards, the decision on PPPs fell to federal authorities (not regional). Its role was not a direct effect of the PPPR regime.
- Stage 2 decisions on PPPs not automatic but discretionary.
- Also rejected ideas that Art. 9 Aarhus Convention should be relied upon to interpret TFEU Art. 263 standing rules more widely (hierarchy of norms).

Emergency measures

C-514/19: on French emergency measures prohibiting neonicotinoids

- French TRIS *notification* in 2017 made to Commission of draft national law (amendment to Code) - prohibition on PPPs containing neonicotinoids and seeds treated (made no reference to PPPR).
- Comm. covered same substances by May 2018 Implementing Regulations bans (except greenhouses) applying from Dec 2018. French Decree (supplementing the Code) adopted, applying also to *same* substance as would be subject to EU ban, but earlier from 30 July 2018.
- National Crop Protection Assoc. challenged French measures on the *same* substances as incompatible with PPPR rules on “other emergency measures” (Art. 71 PPPR), even though there had been a TRIS notification.
- TRIS communications on prohibitions of active substances must be regarded as meeting Article 71(1) PPPR procedures IF:
 - the communication contains a **clear presentation of the evidence** showing, first, that those active substances are likely to constitute **a serious risk** to human or animal health or to the environment and, second, that that **risk cannot be satisfactorily controlled** without the adoption, as a matter of urgency, of the measures (i.e. tests in Article 69); AND
 - the **Commission failed to ask** that Member State IF that communication must be treated as the Article 71(1) information provision. (Flexibility on form if content satisfactory. No incentive to ignore relevant info.)
- May 2018 Implementing Regs. could not be regarded as taken by the Commission *in response* to the TRIS notification (because not based on Articles 69 or 70 PPPR).

Renewal Procedures

C-574/18: on non-renewal decision on AS

- Applicant claimed the **reasons for the finding of a “high risk” for aquatic organisms and earthworms** were insufficient and erroneous. Court concluded non-renewal was actually based on ‘data gaps’ (including for earthworms and aquatic organisms) but not on the ‘high risks’ associated.
- **Seven non-finalized issues**, EFSA’s position preferred to rapporteur MS. Court said this was even if there was a failure to explain this, it was not sufficient to annul because both agreed that there were numerous data gaps.
- **Commission relying upon EFSA error of identifying a data gap** was basing itself on a manifestly inaccurate conclusion BUT this had no impact on legality BECAUSE does not disprove the *other* data gaps which prevented EFSA finalising the assessment of the risks in the other areas.
- Confirmatory data rules in Art. 6(f) and point 2.2. of Annex II PPPR: **No legitimate expectation** that the data which EFSA considered to be gaps **would be requested as confirmatory data** after renewal of the approval (as proposed by the rapporteur MS). No precise assurances given to lead to a justified expectation.
- Not disproportionate even if 5/6 renewals in 2016 issued with conf. data requirements. Applicant had not shown those situations were comparable.
- Declaration of an **admissible dossier by rapporteur does not mean EFSA can no longer question** completeness.
- No breach of **precautionary principle** because cost-benefits to non-renewal were taken into account.