VIA EMAIL

To: European Commission

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11 December 2018

Re: Call for action on unreasonable delays and lack of transparency in the adoption of authorisations and restrictions under REACH

On behalf of ClientEarth, we sent you a letter on 7 June 2018 highlighting unreasonable delays and transparency issues in the adoption of authorisations and restrictions under the REACH Regulation. We appreciate the attention given by your services to our analysis, and the discussion we had on our recommendations in our meetings on 26 June and 17 October 2018. We also thank you for your written reply of 4 July 2018 (the "Letter"). With this letter, we would like to acknowledge the progresses made following our exchanges, stress the need for more actions and answer the Letter in more details.

First, we would like to highlight that, while we agree that the REACH Regulation is "*the most advanced and comprehensive chemical legislation in the world*" as the Letter celebrates, this does not mean much if its implementation is not up to the standard of the legal text. When it is not, both the reputation of the EU and the main objective of this legislation – the prevention of harm to human and environmental health - are undermined.

Delays in taking decisions may lead to a longer exposure to dangerous chemicals in conditions that are not adequately controlled. It may also lead to an unduly extended occupation of the market by chemicals that are dangerous for health and the environment, undermining the development of safer alternatives. The prevention and proper management of delays therefore have to be made a priority.

We would like to acknowledge the **progresses** made to remedy the delays and improve transparency since our initial letter in June. In particular, we welcome:

1. Your commitment to remedy the backlog of authorisations by the end of 2018. *We will be closely following your efforts to do so.*

2. Your work towards the adoption of new internal working arrangements within the Commission to ensure compliance with the REACH 3 months deadline for new incoming cases. *We would welcome a clear communication on what the changes are, when they will be adopted and how you think they will remediate the situation.*

3. Your commitment to improve transparency on the work plan of the REACH committee (informing on the dates when preliminary discussions, discussions and votes are planned, for each authorisation and restriction) by: (i) systematically providing it in writing to CARACAL observers, and (ii) considering how to make it available on a platform accessible to the wider public. *We would welcome further information on when and how you will take this next step.*

While these commitments are welcome, we would also like to highlight the **need for further commitments** on the following points:

1. **Avoid delays in the future**

   Respecting legal timelines must not impair the level of scrutiny of each file, and must not mean more leniency. The responsibility of the decision rests on the Commission in the end, which makes it the institution responsible for adopting authorisation and restriction decisions that ensure the high level of environmental and health protection aimed at by REACH.

   In practice, for authorisations, this means that in addition to better internal arrangements to process the cases, the priority needs to be on improving the quality of the applications. This entails:

   - ☞ Creating the conditions that will fully convince companies to submit to ECHA applications containing information that is precise, relevant and exhaustive enough to properly and efficiently assess them against the criteria set by REACH;
   - ☞ Rejecting inadequate applications in order to clearly indicate to potential applicants that only complete, precise and adequate applications should be submitted– the Lanxess application is a good example of inadequate application;
   - ☞ Stopping to over-rely on the information provided by the applicants, by, for example, reaching further to relevant third parties;
   - ☞ Maintaining the burden of proving that the conditions set by REACH are fulfilled on the applicant, in application of REACH.

   Detailed recommendations on key aspects of these points can be found in the ChemSec/ClientEarth factsheet on ‘how to find & assess alternatives’. *We would*

welcome further exchanges to discuss how our recommendations could be integrated in the current practice.

2. **Better handle potential backlog of authorisation decisions in the future**

   As you explained in your letter and in our meetings, backlogs may happen when many applications are submitted at the same time, when the cases are complex or for other reasons.

   When this happens, prioritisation of the applications made by companies that have missed the deadlines, which has happened in the past, is not acceptable from a legal or policy point of view. REACH's main objective is the protection of health and environment. Any prioritisation should therefore be based on the necessity to act quickly to better protect health and environment.

   This is the case for example when, according to RAC, the risk management measures proposed by the applicant are not sufficient, and thus additional measures need to be imposed to limit the exposure of people or environment to the substance of very high concern. *We are looking forward to further exchanging on this.*

3. **Transparency in the decision making**
   In addition to the commitments described above, the Commission needs to offer more transparency on the reasons why delays happen.

The Letter indicated the Commission's "*intention to develop a set of actions with a time-line aimed to address and steadily reduce the delays".* For all the points above, we would welcome a detailed list of actions with a time-line.

You will find in the Annex more detailed recommendations on some of the points covered above, as well as detailed reactions to the points raised in your Letter.

We welcome the willingness of the services of the Commission that we have met to discuss our recommendations. We would welcome another meeting in early 2019 to continue our discussion.

Yours sincerely,

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Annex

1. Transparency: the current practice does not go beyond the minimum requirements

In the Letter, you refuse to consider our requests to increase the transparency of 1) the draft adoption process 2) the reasons for delays, arguing that the Commission is subject to specific confidentiality rules and in any case goes already beyond the minimum requirements applicable.

A closer look at the applicable law leads however to another conclusion.

a) There is no 'confidentiality rule' that prevents the Commission from ensuring the transparency needed

In the Letter, you mention a "*confidentiality rule*" that would apply to the internal decision-making of the Commission "*as recognised by the exception contained in Article 4(3) of Regulation 1049/2001*".[1]

If it is true that the Commission may refuse to grant an access to document request when it can prove that disclosure would actually, seriously and specifically undermine the decision making process, it is legally unsound to consider that this exception is the expression of a 'confidentiality rule'. The only 'rule' applicable in EU law in that regard is the requirement to ensure the widest transparency possible, both proactively and in response to access to document requests.

This is obvious from the fact that the Court of Justice of the EU (the Court) has consistently affirmed about exceptions to confidentiality that as they "*depart from the principle of the widest possible public access to documents, they must be interpreted and applied strictly*".[2]

It is also clear from a recent case that the Commission should be particularly vigilant to ensure transparency when it is acting in a 'legislative capacity'. For the avoidance of doubt, when referring to the EU institutions legislative capacity, Recital 6 of Regulation No 1049/2001 specifies: "*including under delegated powers*" – it therefore covers the adoption of authorisation and restriction decisions. The Court affirmed that:

> "*The possibility for citizens to scrutinise and be made aware of all the information forming the basis for EU legislative action is a precondition for the effective exercise of their democratic rights as recognised, in particular, in Article 10(3) TEU.*"[3]

This means that in the context of an access to document request, as well as in the context of proactive dissemination, there is no general rule of confidentiality regarding documents drawn up by an institution for internal use. This is especially not the case when the institution is acting in its legislative capacity under delegated powers, such as in the context of the REACH committee.

[1] Commission Letter p. 4
[2] Judgment of 13 July 2017, *Saint-Gobain Glass Deutschland* v *Commission*, C-60/15 P, §63 and the case-law cited. See also Judgment of 4 September 2018, ClientEarth v Commission, C-57/16, §80.
[3] Judgment of 4 September 2018, ClientEarth v Commission, C-57/16, §84

On the contrary, the principle of good governance requires the Commission to disseminate key information proactively. This was explained as follows in a decision of the European Ombudsman:[4]

> *"42. Public access to documents and information held by the EU institutions is an essential component of openness. It empowers citizens to monitor and scrutinise effectively the exercise of the powers vested in the EU institutions. […]*
>
> *46. […], the principle of transparency, or openness, implies that the EU institutions should proactively identify what information the public needs and then disseminate that information in a manner that the public can easily understand."*

Information on which authorisation and restriction decisions will be next discussed/voted, as well as the information on why certain cases are delayed or on the contrary prioritised is essential to 'monitor and scrutinise effectively the exercise of the powers' vested in the Commission. We therefore invite you to reconsider your assertion that transparency on this information is not needed nor required.

Regarding the information on the Commission and the REACH Committee work plan, we welcome the commitment taken during the October meeting that the work plan made available to CARACAL observers will, from now on, provide details per authorisation and restriction cases planned to be tabled for upcoming REACH committees. In the last CARACAL meeting in November we did have access to this detailed work plan which revealed which cases will be discussed or voted on in the next REACH committees. This is a welcome development. The key information missing is the date at which the draft decision will be published on the comitology register. *We look forward to hearing your thoughts on this.*

We also welcome the fact that you considered to make this information available on a platform more public than CARACAL's, and look forward to a precise commitment on that matter.

On this point, it is important to note that the CARACAL, as an "expert group" has to follow the horizontal rules on expert groups. According to these rules (Article 26), a lot more than what is currently published need to be published (such as minutes, and participants' submissions) "*either on the register of expert groups or via link from the register to a dedicated website where this information can be found. Access to such website shall not be submitted to user registration or any other restriction*". The rules even specify "*departments shall ensure publication of the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes"*. Currently, the CARACAL documents that fit the list set in Article 26 of these horizontal rules, including the plan of decisions tables for vote or discussion in upcoming REACH Committees, are only available through CIRCA which requires a registration. This goes against the horizontal rules on expert groups.

Regarding transparency on the reasons for delay and prioritisation of some cases, this could be explained orally in the CARACAL, when the REACH committee work plan is presented. This option in our opinion strikes a fair balance between the transparency objective,

[4] https://www.ombudsman.europa.eu/en/decision/en/11360

and not creating additional burden on the Commission's service. *We look forward to hearing your thoughts on this.*

b) The need to improve the comitology register

Regarding Regulation 182/2011, the Letter states that draft individual authorisation decisions and draft proposals for restrictions are made publicly available before the Committee has voted on those, and suggests that this practice already goes beyond what is required by this regulation. However, this is not the case. Article 10(1) does require the publication of both (i) the draft act "on which the committees are asked to deliver an opinion" (Article 10(1)(d)) which implies before the vote; and, (ii) the final draft "following delivery of the opinion of the committees" (Article 10(1)(f)). Interpreted in light of the general principles on transparency, Article 10 therefore requires to:

- Systematically publish the draft before it is discussed **specifying the date at which it is published**. Today, the drafts are published in the register, as well as the dates of submission of each draft to the Committee, which we welcome. However, currently, the register does not indicate the date of publication of the draft (and it is impossible to anticipate when a draft will be published - see section a) above).

- Publish the draft, final version and full legislative history in **a user-friendly way**. Today, this information is available, but is organised in a way that makes it challenging to find and keep track of the entire history (from the first version to the version adopted). Ideally, this comprehensive overview should be accessible when searched using the name of the company applying for the authorisation, the name of the substance or via the records of the REACH Committee meeting.

  Currently, for authorisations or restrictions:

  → It is not possible to search with the names of the company for earlier authorisations, as the names of the companies were not included in the title of the document. We understand this is now resolved since the names of applicants are now systematically included. We welcome this practice which should be maintained.
  → Folders are organised per version of the draft decision, and thus, the individual folders do not give a complete overview of the history of the measure, i.e. from the first draft that was submitted, to the draft adopted. It is possible to reconstruct this information with the numbers of the folders but is really not user friendly and makes it difficult to keep track of a given case.
  → When searching by committee meetings, the only folders showing are those relating to that meeting and thus not the potential previous "versions" of the same measure.
  → Cases that are "pending" (i.e. Opinions of RAC and SEAC have been submitted to the Commission), do not appear in the register when no

draft measure has been published yet, which makes it difficult to keep track of upcoming cases.

An easier access to the documents and a better interconnectivity between them are needed.

Recommendations for improvement

Publication of a detailed work plan

- ☞ Including the date at which a draft can be expected to be published on the register
- ☞ Systematically disseminate in written form to CARACAL, and make the relevant CIRCA access public without registration or publish the same document on an open platform

Transparency on the reasons for delay & prioritisation

- ☞ Clear oral communication during CARACAL

Publication of draft, final version, relevant dates and full history

- ☞ Improve easiness of access/ user experience in Comitology register

2) Fact-checking

In this section we would like to react to some of the arguments you developed to challenge our analysis, particularly concerning the reasons for delay and the existence of a prioritisation of certain cases.

a) The alleged reasons for the delays

We welcome the acknowledgment in the Letter and during the October meeting that there have been serious delays in processing some authorisations and restrictions and that the Commission's internal working procedures are at least partially responsible for the unreasonable delays.

However, we disagree with some of the arguments you used to justify the delays.

(i) The alleged necessity to wait for a parallel restriction to be adopted

Article 58(6) provides that "*a substance listed in Annex XIV may be subject to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in an article*". **So any authorisation granted would be**

applicable only in so far as it complies also with the new restriction. Delaying a decision regarding an authorisation, to "*ensure consistency of the final authorisation decisions with the restriction*" (Letter p.3) is therefore not necessary nor justified.

While we have noted the positive vote, in July, in favour of the restriction, we also noted that at the REACH committee of September, *t*he Commission made a presentation on the further planning for the Grupa and Deza cases. We would like to hear more about this "further planning" as we still do not understand the reason for these further delays.

In particular, regarding the DEZA case, no draft decision has been published yet on the register[5] so we cannot verify how the restriction and "new information provided" is affecting this authorisation and could justify that this authorisation was put on hold.

(ii) The impact of international obligations

Regarding restrictions, we appreciate the need to add to our analysis of the timeline WTO constraints. However, this should have no bearing on the time the Commission needs to "prepare" the draft set in REACH at maximum 3 months. In any case, running the numbers again adding these 2 months for mandatory standstill of **WTO**, the bar for "reasonable time" would be set at 12 months, there are still a majority of cases (58%) which took more than 12 months to be adopted.

(iii) The impact of the need to translate the final version

Finally, thank you for providing insights on internal procedures and in particular the need to factor time for **translation** in all Member States languages. However, it is very clear that when there are delays, these happen before the draft is submitted to the Committees and not after. This means that the main source of the delays is the work of the Commission between the moment it receives the opinions from RAC and SEAC and the moment it submits the draft to the REACH committee.

b) The prioritisation of authorisations for which the companies applied after the last application deadline

The Letter states that "*in preparing draft authorisation decisions and draft restrictions, the Commission follows the chronological order in which it receives the opinions from the ECHA Committees*". However, we integrated to our analysis the dates at which the Commission has submitted the first draft authorisations to the Committee, and this new data confirms that in many instances, this chronological order was in fact not followed.

Some cases benefit from a prioritisation, and not the cases that should be prioritised if environment and human health are the main concerns.

For example, in the Yara France case, RAC/SEAC opinion is dated from January 2015 and the Commission submitted a draft to the REACH committee in May 2015. By comparison, in the *Linxens* case, RAC/SEAC opinion is dated from October 2014, but the Commission

[5] Last connection on the register on 6 December 2018

submitted a draft to the REACH only in June 2015. If the Commission had followed the chronological order, it would have proposed a draft to the REACH committee in the Linxens case, before the Yara France case.

A striking difference between these two cases is that in Yara France failed to apply for authorisation on time (before the last application deadline), and thus was not allowed to use the substance of very high concern until a decision was taken.

Another example of such practice is the Gruppo Colle case. In this case, as explained in our initial letter, and again at the October meeting, this case shows without doubt that the Commission has prioritised the cases where companies applied after the last application deadline and would thus not be allowed to use the substance of very high concern anymore if a decision was not adopted before the sunset date.

In Gruppo Colle, the Commission received the opinion of RAC and SEAC in fact *after* the opinion in the Ormezzano case, and yet adopted the decision in the Gruppo Colle case a long time before the Ormezzano decision. The Commission has been particularly prompt in submitting a draft decision to the REACH committee in the *Gruppo Colle* case: **only 2 months** after the reception of the RAC/SEAC opinion. By comparison, the Ormezzano case is still pending: it is only at the September REACH committee that a draft was discussed.[6]

These two cases are very similar in terms of uses covered, scope and analysis needed. The only remarkable difference is that Gruppo Colle missed the last application deadline. On the basis of these facts, the only logical conclusion is that the Commission has decided to fast track this case, on the basis of concerns other than urgency to protect human health and the environment, but rather due to urgency in saving a business from its own negligence.

In the meeting held on 26 June, the Commission explained that the differences in timing of these two cases where based on the fact that the Commission asked some questions to ECHA on both cases, and in the Gruppo Colle case, ECHA responded more quickly. It is not possible, on the basis of publicly available information to verify these facts. We would welcome more details and evidence of the exchanges you had with ECHA on these two cases. However, the two cases being very similar, this argument does not explain why Ormezzano is still not being decided while Gruppo Colle has been handled a long time ago.

3) Actions needed to avoid future backlogs in authorisation decisions

in the letter as well as during the meetings, you argued that many delays were due to the fact that some cases are “more complex than others”. We understand from the October meeting that what is understood as ‘complex’ are the cases where the final decision is difficult to take because the applications are of bad quality: the use applied for is too broad, information is lacking, little visibility is acquired on what the real life impacts are, etc. These issues are particularly acute with what is often called “upstream” applications.

[6] According to the summary record. The draft decision however is not published in the comitology register (see the September meeting folder : http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.dossierdetail&Dos_ID=16610&dos_year=2018&dc_id= (last accessed on 5 October 2018)

We would like to remind the Commission that REACH does not create a more lenient regime for "upstream" applications. If companies up in the supply chain want to apply for an authorisation covering uses relevant for companies downstream they need to know how their product is going to be used further down the line. They also need to provide enough information to allow ECHA's committees and the Commission to verify that the conditions for granting an authorisation are met. Granting an authorisation to companies that do not provide the necessary information is equivalent to granting a blank check, putting potentially workers, the general public and the environment at risk, in breach of the law.

To solve the issue of these 'complex' applications, it is indeed indispensable, as noted in the Letter, to work with ECHA to improve the quality of the dossiers. We would like first to provide some recommendations on what could be done in that regard.

However, in order to convince the companies to send adequate information, it is also indispensable to create an incentive, a clear signal that only truly complete applications can be successful. This is why we call on ECHA, the Commission and the Member States constituting the REACH Committee, to reject the applications that are simply not good enough - either because they do not pass the conformity test or do not meet the conditions for authorisation set by REACH - rather than remaining stuck in their analysis for months or years.

a) Working with ECHA and Member States to improve the quality of the applications

The Letter informs us of your plan to work with ECHA and the Member States to improve the quality of applications, without giving details on the timeline, the type of actions considered or the ones already completed/planned. We would welcome more details.

A first action that needs to be done is the reform of the templates that the Applicants have to use when submitted their applications. These templates, among other changes, have to reflect better ECHA's guidelines on 'How to develop use descriptions in applications for authorisation'.[7] This will help giving clearer indications on which information is necessary, particularly in relation to the analysis of alternatives.

A second involves to rely further on third party information in order to be able to catch the potential bias or gaps in the information submitted by the Applicants.

On those two points we would like to invite you to consider the recommendations of a paper we wrote with ChemSec on 'How to find and assess alternatives'[8]

b) Reject applications that are not conform or do not meet the authorisation criteria

In order to send a strong message to the future applicants, and motivate them to choose the best application strategy possible, it is essential to not authorise applications with structural issues.

[7] ABC guidelines adopted in June 2017, see https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf

[8] See ChemSec and ClientEarth factsheet 'How to find and analyse alternatives in the autorisation process', 2018.

This means, in practice, that SEAC and RAC should not let applications with crucial information gaps pass the conformity test. SEAC and RAC should also not hesitate to recommend the rejection of applications that are too broad, vague or imprecise to assess whether the conditions set by REACH are met.

Finally, the Commission has the final responsibility to grant or not grant authorisation, in line with the conditions set out in the legal text. Thus, we encourage the Commission to reject authorisations when the data is of such poor quality that it extremely difficult to assess whether the conditions set by REACH are met. REACH places the burden of proving that the conditions it sets to obtain an authorisation are met on the companies, that have the legal obligation to bring precise, detailed, relevant and sufficient information. It is legally and practically necessary to hold companies to their obligation. This will have the double benefit of remedying the backlog, and sending a strong signal to companies that they need to improve their applications. The current situation leads to rewarding companies with more time, when their applications are in fact not adequate – the *Lanxess* case is a good illustration of this problem.

This is even more necessary than more time spent on the draft cannot solve a structural problem in the application. For example, it took the Commission 18 months to submit to the REACH Committee the draft authorisation decision in the DCC case (lead chromate). The final decision has obvious flaws that result from the weakness of the application. It now faces two Court cases that are still ongoing.

Similarly, the Commission needs to use its power to withdraw an authorisation in case of a change of circumstances (Article 61 REACH), when it is revealed that the application did not contain, voluntary or not, information crucial for the assessment against the criteria set by REACH – for example information on an available alternative dissimulated by the applicant. This will create an incentive to send accurate and exhaustive information.

Recommendations for improvement

- Improve the quality of the applications for authorisations and the quality of their assessments by, among others actions:

  - ☞ Improve templates used by companies to apply for authorisation
  - ☞ Gather and use more information from third parties
  - ☞ Undertake actions to better find and assess alternatives as recommended in ChemSec and ClientEarth's factsheet
  - ☞ Use power to reject applications which are clearly not fulfilling the conditions set by REACH or do not contain sufficient information to determine if they do
  - ☞ Use power to withdraw authorisation when it is revealed that key information was missing from the application

4) Action needed to better handle potential future backlog in authorisation decisions

We appreciate the commitment you made to clear the existing backlog and the hope that the measures taken will avoid the creation of a backlog in the future.

However, backlog may still happen when the Commission will have to face a heavy wave of applications, potentially containing a few that would be either politically sensitive or technically difficult.

If this becomes the case, it might become necessary to prioritise some cases. We would like to reaffirm our strong opposition to the prioritisation of the cases where the Applicants missed the deadline to apply. This prioritisation serves the interest of that specific company but is both unfair to the companies applying on time and a reward to negligence (see section 2 c).

However, we strongly encourage the Commission to prioritise the dossiers where delays in decision-making are detrimental to human health or the environment. It is not rare for RAC to identify the need for additional risk management measures compared to the ones already put in place by the Applicant. Each day of delay is in that case a day where the Applicant is not submitted to a legal obligation to implement those additional risk management measures. It is indispensable to make sure that this situation is solved as quickly as possible to limit the exposure of people and environment to the chemical at stake.

Recommendations for improvement

- ☞ Consider a prioritisation of the applications for authorisations for which RAC identified the need of additional risk management measures in case of backlog.