Európsky ombudsman

Rozhodnutia o oneskorení Európskej komisie v spracúvaní spisov o reprodukčnej toxicite chemických látok (OI/2/2016/RH)

Rozhodnutie
Prípad OI/2/2016/RH - **Otvorené dňa** 16/02/2016 - **Rozhodnutie z dňa** 18/07/2017 - **Dotknutý orgán** Európska komisia (Nie je oprávnenie na ďalšie informácie) |

Toto vyšetrovanie z vlastného podnetu sa týkalo prieťahov v spracúvaní spisov o možnej reprodukčnej toxicite 216 chemických látok podľa nariadenia č. 1907/2006 o registrácii, hodnotení, autorizácii a obmedzovaní chemikálií (REACH).

Jedným z hlavných cieľov nariadenia REACH je zlepšiť ochranu ľudského zdravia a životného prostredia pred rizikami, ktoré prinášajú chemické látky. Na dosiahnutie tohto cieľa sa v nariadení vyžaduje, aby podniky vypracúvali informácie o chemických látkach, ktoré vyrábajú alebo dovážajú. V tomto nariadení sa propagujú aj alternatívne metódy na hodnotenie nebezpečnosti látok, aby sa minimalizovalo testovanie na zvieratách.

Z dôvodu nezhôd v otázke typu skúšok, ktorých vykonanie by sa malo od podnikov vyžadovať, sa od roku 2011 v Európskej komisii zhromaždil veľký počet nevybavených prípadov. Komisia sa rozhodla odložiť rozhodnutia o týchto prípadoch, pokiaľ nebude schválená nová dostupná a preferovaná testovacia metóda a kým Európska chemická agentúra (ECHA) nevydá príslušné usmernenia.

Vo februári 2016 ombudsmanka začala vyšetrovanie z vlastného podnetu, aby zabezpečila, že rozhodnutia v nevybavených prípadoch sa príjmu čo možno najskôr. Plne funkčný testovací systém, ktorým sa vygenerujú nové údaje a doplnia chýbajúce informácie o nebezpečných účinkoch chemických látok, je mimoriadne dôležitý na to, aby sa plne využil potenciál nariadenia REACH. To platí zvlášť v prípade reprodukčnej toxicity, lebo obavy a chýbajúce informácie týkajúce sa účinkov na reprodukciu patrili medzi hlavné témy diskusií, ktoré viedli k príprave nariadenia REACH. Potreba rýchlo konať je o to naliehavejšia, že agentúra ECHA nemôže pokračovať vo vybavovaní nedoriešených prípadov, pokiaľ Komisia nedokončí prebiehajúci postup. Prijímanie rozhodnutí v prijateľnom časovom rámci je tiež jeden zo základných princípov dobrej správy vecí verejných.

Ako z vyšetrovania vyplynulo, hoci si Komisia v celom postupe sama stanovila celý rad termínov, nedodržala ich. Vzhľadom na zložitosť otázok a neobvykle vysoký počet prípadov, ktoré musela spracovať s obmedzenými zdrojmi, však vyvinula mimoriadne úsilie, aby

zabezpečila dobrý rozhodovací postup v súlade s právnymi predpismi, administratívnu efektivitu a zohľadnila vstupy od všetkých zúčastnených strán. Ombudsmanka víta pokrok, ktorý Komisia dosiahla od začiatku vyšetrovania. V rámci vyšetrovania sa takisto zistil systémový nedostatok podnetov k tomu, aby si registrujúci aktualizovali svoje dokumentácie, a to aj napriek tomu, že je to ich povinnosť. Tejto otázke by sa malo venovať prebiehajúce hodnotenie nariadenia REACH.

Glossary

General [1]

European Chemicals Agency (ECHA): The EU agency which helps implement EU chemicals legislation, including REACH, by helping companies comply with the rules, advancing the safe use of chemicals, providing information on them and dealing with chemicals of concern.

REACH: Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals. The regulation was adopted by the European Parliament and the Council and entered into force on 1 June 2007. It aims to improve the protection of human health and the environment from the potential risks of chemicals, while enhancing the competitiveness of the EU chemicals industry. REACH also promotes alternative methods for the hazard assessment of substances to reduce animal testing.

Registrant: A manufacturer or importer who seeks to register a chemical with ECHA under REACH.

Tests and checks

Compliance check: ECHA may examine any registration file to verify if the information submitted by registrants is compliant with the legal requirements. Compliance checks evaluate the substance identity description and the safety information in the file including the chemical safety report or specific parts of the file, for example the information related to the protection of human health.

Extended One-Generation Reproductive Toxicity Study (EOGRTS): One generation of vertebrate animals is used to test the effects of chemicals on fertility and growth. The basic one-generation study can be expanded by testing a second generation.

Registration dossier/file: A file provided to ECHA with technical information on chemicals that are produced or imported and, when required, a chemical safety report.

Testing proposal: Testing on vertebrate animals is the last resort for obtaining missing information on a substance and to be able to meet REACH information requirements. ECHA studies all the proposals to check that reliable and adequate data will be produced and to prevent unnecessary animal testing.

Two-Generation Reproductive Toxicity Study: Two generations of vertebrate animals are used to test the effects of chemicals on fertility and growth.

Committees and expert groups

CARACAL: A Commission expert group with representatives from the Commission, ECHA, Member State authorities and stakeholder groups. It stands for 'Competent Authorities for Registration, Evaluation, Authorisation and restriction of Chemicals and Classification, Labelling and Packaging' (in other words, Competent Authorities for the REACH and CLP Regulations). The expert group's mission is to cooperate with the Commission and ECHA to implement these Regulations.

Member State Committee (MSC): A committee within ECHA consisting of EU Member State representatives that participates in several REACH processes. When Member States propose amendments to ECHA draft decisions on testing proposals and compliance checks, the MSC seeks unanimous agreement.

REACH Committee: A 'comitology' committee consisting of EU Member State representatives, which assists the Commission in taking decisions to implement REACH, such as a decision on a registrant's testing proposal.

The background to the inquiry

1. This inquiry looked at the reasons for, and implications of, delays by the European Commission in dealing with the potential reproductive toxicity effects [2] [Prepojenie] of 216 chemical substances. The Commission is required to deal with these matters under Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (the Regulation is widely referred to simply as "REACH") [3] [Prepojenie].

2. One of the main objectives of REACH is to improve the protection of human health and the environment from the risks posed by chemicals. REACH seeks to achieve this objective by requiring producers and importers of chemicals to register the chemicals they produce or import and gather information on them. [4] [Prepojenie] This may include conducting tests to fill information gaps on the hazard effects of chemicals with a view to ensuring safe use, managing potential risks and replacing chemicals of high concern over time with safer alternatives. Companies communicate the required information, including proposals to conduct any new tests, to the European Chemicals Agency (ECHA) through their REACH registration file. ECHA evaluates the files to approve testing proposals or to check that the information submitted by registrants complies with the legal requirements. One of the issues it checks for relates to animal testing, and in particular whether there are alternative methods for the hazard assessment of substances to reduce animal testing.

3. ECHA then prepares draft file evaluation decisions which are submitted to its Member State

Committee (MSC). If the MSC cannot reach a unanimous agreement on a draft decision, the file is referred to the Commission, which is assisted on the matter by a “REACH Committee”, also composed of Member State representatives. After consultation within the Commission on draft decisions prepared by DG Environment (in consultation with DG Internal Market, Industry, Entrepreneurship and SMEs), Member States can submit comments. If the REACH Committee votes in favour, the Commission can adopt the final decision.

4. Between 2011 and 2014, ECHA transferred 216 files concerning potential reproductive toxicity effects to the Commission because ECHA’s MSC had not reached unanimous decisions on which specific test(s) to require from registrants. The Commission then put off taking decisions on those files until an update of the relevant REACH Annexes made the newly available Extended One-Generation Reproductive Toxicity Study (EOGRTS) mandatory. The EOGRTS is expected to provide more valuable scientific information and require the use of fewer animals than the old standard test method (the Two-Generation Reproductive Toxicity Study).

5. The Ombudsman opened her inquiry [5] [Prepojenie] in February 2016 to help ensure that the decisions on the pending cases would be taken as quickly as possible, especially bearing in mind that the regulatory change needed to unblock the decision-making process (namely, the prioritisation of the EOGRTS) came into effect in March 2015. By February 2016, some registrants had been waiting up to five years for a decision .

The inquiry

6. After receiving the Commission's reply [6] [Prepojenie] to the Ombudsman’s letter opening the inquiry, Ombudsman staff met with the Commission to clarify issues falling within the scope of the inquiry and to understand fully the Commission’s ongoing processes. [7] [Prepojenie]

7. Among the most important points to emerge up to this point in the inquiry were the following:

Implications of the backlog for the objectives of REACH: The Commission stated that the ongoing delays do not negatively affect companies placing substances on the market, as companies can continue with their operations pending the outcome of the evaluation under REACH. The delays are also expected to have limited effects on human health because, during the time that data are still being generated (via testing or compiling existing sources of information), registrants are required to manage risks and take precautionary measures to ensure that their substances do not adversely affect human health or the environment.

Dealing with the pending cases after the regulatory change: Even though the changes to the REACH Annexes took effect in March 2015, the Commission decided to process the pending cases only after ECHA had adopted guidance for registrants on how to satisfy the new information requirements. This guidance was finalised in July 2015. The guidance includes detailed information on when the standard EOGRTS study design needs to be expanded by further test packages [8] [Prepojenie]. The Commission then developed an approach whereby it

organised cases into groups that could be addressed by a single decision. It used a cut-off date of 31 January 2016 to assess all the pending files for updates from registrants. This grouping and assessment of cases led to the Commission drawing up 16 draft decisions to deal with all the pending cases.

Substance of the Commission's draft decisions: For the most part, the Commission's draft decisions reject the pending proposals as the original files, based on the old test method, no longer meet the legal requirements. Most decisions, when made formally, will require the registrants to submit to ECHA, within 90 days of receiving the Commission decision, an updated file for the substance concerned based on the new information requirements. This means, in practical terms, ECHA starting the evaluation process over again. The Commission expects that ECHA's guidance for registrants should help expedite matters.

Expected timeline for adopting the Commission decisions: Following a discussion in the REACH Committee in September 2016, the draft Commission decisions were sent to registrants and Member States for comments. At that stage, the REACH Committee was expected to come to a decision on most of the cases in December 2016, allowing for the adoption of the final Commission decisions in early 2017 (by written procedure that takes around two months).

8. Having reviewed the material in the case-file, the Ombudsman wrote [9] [Prepojenie] to the Commission to convey that she was considering a finding of maladministration relating to the delay on the part of the Commission in communicating directly with registrants once the necessary ECHA guidance was finalised. Given that some files had been pending since 2011, the Ombudsman's view was that the Commission —as ECHA did in the case of 40 registrants whose testing proposals it was examining — should arguably have contacted all registrants whose cases were pending before it to request them to check and, if necessary, update their registration file.

9. The Ombudsman's understanding was that the earlier the Commission contacted the registrants, and requested a review of the information they had already provided, the sooner the registrants would have been put on notice that they needed to review and update their information. This could have helped avoid further delays in the implementation of REACH in that more registrants could have provided all the necessary updates, with the result that ECHA would be in a position to move forward with the file evaluations more rapidly.

10. A further meeting took place between Commission and Ombudsman staff [10] [Prepojenie], following which, on 31 March 2017, the Commission sent its detailed written response [11] [Prepojenie]. Among the most important points to emerge in response to the Ombudsman's letter, signalling a possible finding of maladministration, were the following:

11. According to the Commission, the approach taken, with the support of Member States' Competent Authorities and stakeholders, is the one that best ensures the implementation of the general principle of good administration. It allows for an otherwise complex and cumbersome decision making procedure to be shortened and simplified (that is, it avoids the administrative processing of 216 individual measures). It provides the best scientific result in the shortest time

and brings clarity and legal certainty to registrants. This is in view of the complexity of the issue, both scientifically and in terms of the changes to the applicable legislation; the unusually large number of cases the Commission has to handle with the limited resources available; and the need to avoid sending an unnecessary and misleading communication to registrants. The time invested in ensuring that the most appropriate choices are made, and in securing the support of all the actors involved for the proposed way forward, allows the Commission to gain time in the final stages of the process. The Commission provided further detail on its actions between July 2015 and January 2016.

12. In response to the Ombudsman's suggestion that the Commission should have contacted registrants individually at an earlier stage, the Commission replied that the legislative change was widely disseminated and that any letter to a registrant could at most have repeated the general communication on the legislative change already made publicly available. The Commission believes that it has sufficiently informed registrants to enable them to identify the need to perform an EOGRTS, which – in turn – requires them to update their registration file [12] [Prepojenie]. It points out, however, that the way this requirement is formulated in REACH means that it is difficult to enforce and does not provide any incentive for registrants to update their file before they are aware an authority will take a decision. The Commission considered that it was more appropriate to send each registrant the relevant draft Commission Decision requiring further action by it only when that decision had passed the internal consultation stage. These draft decisions could be prepared only once all individual cases were analysed.

13. The Commission also noted the important differences between its role and that of ECHA in processing draft decisions. The Commission does not have the authority to take new testing proposals into account as they are not part of the draft decision referred to it by ECHA. So while ECHA would benefit from updates made by registrants to registration files, an update of the testing proposal to the new EOGRTS would not change the Commission's obligation to decide on the draft decision referred to it earlier. Getting such updates sooner rather than later would not have advanced the procedure of assessing the new EOGRTS testing proposals.

14. In an email sent on 30 June 2017, the Commission set out its updated timeline for adopting the decisions. It has already adopted three decisions, covering 16 cases. It sent the other 13 draft decisions to registrants for comments on 17 November 2016 [13] [Prepojenie] and addressed the comments received. As a result, some draft decisions were withdrawn from the 'grouping' decisions and the individual registrants concerned are being dealt with on the basis of the specifics of their cases. As a consequence the number of outstanding draft decisions increased from 13 to 20. Overall there will be 23 decisions on EOGRTS adopted by the Commission. The 20 outstanding draft decisions were sent for comments to the Members of the REACH Committee in advance of the vote by written procedure. The Commission took on board Member States' comments and redrafted some decisions. The 20 draft decisions have now been submitted to the REACH Committee Members for vote by written procedure. The voting period is now closed for six of them, with unanimity in favour. The internal procedure for Commission adoption by written procedure has started and normally takes two months. These six decisions cover 65 cases. The vote in the REACH Committee on the remaining 14 draft decisions will be taken by 21 July. The draft decisions will then be sent for adoption by the

Commission, by written procedure.

The Ombudsman's assessment

15. REACH was designed, in part, to shift the burden of proof from regulators to industry, among other things, by requiring companies to generate information on the chemicals they produce or import. A fully functioning testing regime generating new data and filling information gaps on the hazard effects of chemicals is of huge importance if REACH is to achieve its full potential. It is in the public interest that REACH is implemented in full and in a timely way. This is particularly important when it comes to reproductive toxicity. [14] [Prepojenie]

16. The Ombudsman opened this inquiry in February 2016 on the grounds that the testing regime for producing new data on reproductive toxicity had been largely inoperative since 2011. This is a significant period of time. The Ombudsman's inquiry does not focus on the time taken by the Commission and the Member States to modify the REACH Annexes to make the EOGRTS mandatory (it was made mandatory in March 2015). The inquiry focuses on what has happened since the regulatory update was finalised and seeks to ensure that the decisions on the pending cases are now taken as rapidly as possible. In deciding on this inquiry, the Ombudsman was concerned in particular about the possible negative consequences for human health as a result of delays in the testing/compliance regime.

Impact of the delay on human health

17. With this in mind, the Ombudsman questions the Commission's view that delays in the testing of chemicals are expected " *to have limited effects on human health* ". The Commission takes this view because registrants are required, in the meantime, to manage risks and take precautionary measures to ensure that their substances do not adversely affect human health or the environment.

18. Such risk management and precautionary steps are necessary, and should, if applied properly, *limit* the possible negative effects on human health of the chemicals in question. However, the risk management and precautionary measures could never replace decisions based on adequate objective tests. Such tests allow registrants and ECHA to measure properly the actual effects of the chemicals on human health (if any).

19. The Ombudsman fails to understand how the Commission can take the categorical view that the effects of the delays are expected to be *"limited"* . The Ombudsman certainly *hopes* that the effects on human health will be limited. However, unless and until tests are actually performed, or the information gaps in question are filled from alternative sources, this cannot be known with certainty. An examination of some of the decisions currently pending before the Commission confirms that there are existing information gaps regarding the reproductive toxicity effects of substances currently in use in the EU. The decisions soon to be taken by the Commission, for the most part, require registrants to submit to ECHA an updated proposal in accordance with the amended information requirements.

20. The Ombudsman understands that the implementation of the new legislative text was also a high priority for ECHA so as to gather hazard information on this crucial human-health endpoint. [15] [Prepojenie]

What is a "reasonable period of time"?

21. Mindful of the fact that the chemicals in question are already on the EU market, with whatever health risks this may possibly entail, the next step is to examine whether the time this process has taken before the Commission is reasonable. While the Commission has stated that Article 51(7) REACH does not impose any legal deadline for it to adopt decisions in this area, the Commission itself acknowledges a certain delay. [16] [Prepojenie]

22. The Court of Justice has established that action within a reasonable time is required even in cases where the applicable texts are silent on the matter. [17] [Prepojenie] This principle is not only a question of "hard law" rights enforceable by a court. The need to take a decision in a reasonable period is a general principle of good administration, which should be applied irrespective of whether the delay confers legally enforeceable rights on a person.

23. The Ombudsman looks at this issue from the perspective of good administration, and not simply from the perspective of enforceable legal rights. It is almost certainly the case that those entities which may have a legal right to challenge the delays, namely the companies that manufacture or import the chemicals in question, are unlikely to challenge the delays. This is because their operations within the EU during these periods are not affected by the delays — they can continue to market the products during that period. Moreover, conducting tests will cost them money. They are unlikely to wish to limit delays since they will not be required to carry out the tests until their testing proposals have been approved. Thus, even if they could challenge such delays before the EU courts, they have no incentive to mount such a legal challenge.

24. The public certainly has an interest in ensuring that an adequate testing regime be put in place in a reasonable period. The question then is: what is, in the present context, a "reasonable period of time"?

25. It is good administration to prioritise and to deal in good time with issues that relate to the protection of human health. It is not good administration for the Commision to have any significant delays in dealing with such cases without very good objective reasons for these delays.

26. The Ombudsman appreciates that it has been challenging for the Commission to find common ground among Member States to enable it to move forward with the pending cases. She is also aware that the delay is, to some extent, linked to efforts to ensure that the best possible scientific data is generated to protect human health. The Commission decisions at issue in this case must be legally sound, scientifically and technically correct and not give rise to an excessive burden in terms of their administrative handling. There is no doubt that much of the effort expended by the Commission throughout this procedure, and documented at length in

its detailed reply to the Ombudsman, sought to meet all of these challenging objectives.

27. At the same time, there should arguably have been a greater sense of urgency within the Commission to complete this process more rapidly. The sooner ECHA is in possession of the updated proposals from registrants, the sooner it can carry out the necessary scientific and technical evaluation and ensure the implementation of REACH in this specific area. [18] [Prepojenie]

28. This implies not only that the Commission should have striven to complete the process of finalising the administrative procedure before it as soon as possible but also that registrants should have been encouraged, to the extent possible, to update their files so that ECHA could start its evaluation on the basis of the most up-to-date information.

29. Despite the Commission's efforts, deadlines were set and missed along the way. The Commission indicated in March 2015 that the individual draft decisions would be presented to the REACH Committee from September 2015 onwards, in an attempt to process all 216 cases over seven consecutive REACH Committee meetings. The Commission subsequently informed the Ombudsman that it was preparing all of the draft decisions with a view to submitting them to the REACH Committee for discussion and vote in summer 2016. This would allow final adoption of all decisions related to the 216 cases at the beginning of 2017. As set out above, the Commission now expects to have adopted all of the final decisions by the end of September 2017.

30. While it is important for an administration to set and seek to meet reasonable deadlines, it is far from ideal, from the point of view of good administration, to continually set and then miss deadlines. The more important question is, however, whether there are good objective reasons for these delays.

Are there good objective reasons for these delays?

31. The Ombudsman has come to the conclusion that, particularly in its detailed reply to the concerns she set out, the Commission has adequately justified the time taken to process these decisions. In view of what the Commission rightly refers to as the complexity of the issue and the unusually high number of cases it had to handle with limited resources, the Ombudsman is reassured that the Commission made particular efforts to ensure legally sound decision-making, administrative efficiency and buy-in from all stakeholders, who range from Member States' Competent Authorities, ECHA, the chemical industry, NGOs and registrants themselves. While it is not possible categorically to endorse the Commission's statement that its approach *"provides the best scientific result in the shortest time"* , neither is it possible to be certain that an alternative approach would have delivered a better outcome. This is notably in view of the Commission's assertion that the *"time invested in ensuring that the most appropriate choices were made and in securing the support of these actors for the proposed way forward allowed the Commission to gain time in the final stages of the process."*

Avoiding further delays in the implementation of REACH

32. Despite registrants having had 14 months to provide the necessary updates (from July 2015 to September 2016, the cut-off date finally used by the Commission), only a small number of registrants did so in such a way that no further action is required of them in the draft Commission decision. [19] [Prepojenie] The overwhelming majority of registrants will therefore have a period of 90 days from the date of receiving the Commission decision in which to provide the full updates to ECHA. This unfortunately will lead to further delays in implementing REACH in that the Commission decisions will, for the most part, require registrants to submit to ECHA an updated proposal in accordance with the amended information requirements. [20] [Prepojenie]

33. This issue needs to be seen against the backdrop of a more systemic problem linked to REACH. It appears to have been the case, for the vast majority of the 216 cases pending with the Commission over a period of years, that the decision which the Commission would eventually give would be a decision requiring registrants to update their registration files (for example, to include a new testing proposal to conduct an EOGRTS). Despite this knowledge, it appears the Commission was obliged to complete a process which inevitably would lead nowhere other than to a conclusion that the registrants would have to start all over again with updates to ECHA and with all that this entails. As the Commission itself points out, the way the relevant requirement is formulated in REACH is difficult to enforce and does not provide any incentive for registrants to update their files before they are aware an authority will take a decision. However, shortcomings in this area are of a systemic nature rather than necessarily being a reflection of insufficient action on the part of the Commission in this particular case.

34. ECHA too has acknowledged this problem pointing out that *"the quality of the data on chemicals needs to be improved and updated whenever there is a material change or where new information comes to light. REACH requires companies to do this already, but it is not being done consistently enough…. This is the most significant barrier to be overcome in terms of reaching the objectives of the legislation. It also leads to wasted time and inefficiencies in Member States, the Commission, ECHA and in companies themselves. So the change needed on the one hand is attitudinal or behavioural on the part of companies, and on the other hand it is for the Commission to consider the need for implementing legislation to further specify these ongoing obligations".* [21] [Prepojenie]

35. In view of the evaluation [22] [Prepojenie] of REACH currently underway, the Ombudsman will make a corresponding suggestion for improvement. Specifically, the Ombudsman invites all those involved in the follow-up to the REACH evaluation to address the systemic shortcoming identified in the current inquiry, namely, the lack of incentives for registrants to update their registration files and the enforcement difficulties that this gives rise to.

Purpose of the Ombudsman's inquiry largely achieved

36. The Commission has, **since the Ombudsman opened her inquiry** , taken concrete steps to finalise its draft decisions on the 216 cases. Between February and September 2016 the Commission concluded its full assessment of the cases. It consulted internally (so-called

‘inter-service consultation’) on the draft decisions addressing all 216 pending cases. Initial discussions took place in the REACH Committee, after which the Commission sent draft decisions to registrants and Member States for comments. The Commission now expects to adopt most of the decisions by the end of September 2017. While the purpose of this inquiry has therefore been largely achieved, the Ombudsman will ask the Commission to report back within three months of the date of this decision to confirm that the Commission’s decisions have indeed been taken.

Conclusion

Given the progress the Commission has made since this inquiry was opened, the Ombudsman now closes the inquiry with the following conclusion and suggestions:

The purpose of this inquiry has been largely achieved.

Suggestions for improvement

The Ombudsman invites the Commission to report back within three months to confirm that the decisions have been taken.

The Ombudsman invites all those involved in the follow-up to the REACH evaluation to address the systemic shortcoming identified in the current inquiry, namely, the lack of incentives for registrants to update their registration files and the enforcement difficulties that this gives rise to.

The Commission will be informed of this decision.

Emily O'Reilly

European Ombudsman

Strasbourg, 18/07/2017

Annex I: How REACH works

Introduction [23]

REACH regulates the registration, evaluation, authorisation and restriction of chemicals in the

EU. Companies must register their chemicals with ECHA, according to different deadlines depending on the quantity and toxicity of the chemical. ECHA checks that files are complete and evaluates some of them, according to pre-defined criteria. A decision may be taken to restrict the use of a chemical or make it subject to prior authorisation.

1. Registrants submit a file on the chemicals they manufacture or import

Companies are responsible for collecting information on the properties and uses of the chemicals they manufacture or import above one tonne per year. They also have to assess the substance's hazards and potential risks. Companies communicate this information to ECHA through a registration file, which contains:
- A technical file including information such as the identity of the manufacturer and the substance; the uses of the substance and if relevant exposure categories; guidance on the substance's safe use; and, of particular relevance to the Ombudsman's inquiry, testing proposals;
- When required, a chemical safety report
- REACH provides for a phase-in regime for existing chemicals according to the deadlines set out below:
- 1 December 2010: Chemicals produced at 1000 tonnes per year/100 tonnes per year if they are very toxic to aquatic organisms/1 tonne per year if they are highly toxic.
- 1 June 2013: Chemicals produced at 100 tonnes per year or less.
- 1 June 2018: Chemicals produced at 1 tonne per year or less.

2. ECHA checks files for completeness

All files submitted to ECHA undergo a number of checks, including an automated check of whether all required fields are filled out and all documents included. If there is no indication to the contrary from ECHA, registrants may start or continue to manufacture or import chemicals. A registrant may also start or continue to manufacture or import chemicals, even where ECHA requests further information. If the file is incomplete and/or the fee payment is missing, ECHA informs the registrant, setting a reasonable deadline. If the registrant fails to adhere to the deadline, ECHA rejects the registration. This decision can be challenged via ECHA's appeal procedure.

3. ECHA evaluates testing proposals and conducts compliance checks

ECHA and the Member States evaluate (i) the information submitted by companies to verify whether REACH requirements are met (compliance check) and (ii) any proposals to test on vertebrate animals. They also seek to clarify if a given substance constitutes a risk to human health or the environment (substance evaluation). After evaluation, registrants may be required to submit further information on the substance.

The procedure for ECHA to evaluate companies' proposals to test chemicals and conduct compliance checks is as follows:

i) Selection

All valid testing proposals are examined. REACH requires ECHA to carry out a compliance check on at least 5% of the registration files of each tonnage band. The file selection is either random or concern-based (targeted).

ii) Scientific and legal assessment

This involves a scientific and legal analysis of the information provided by the registrant. Third parties are consulted on testing proposals involving vertebrate animals and asked to submit existing relevant scientific information on the proposed test. The draft decision produced by ECHA is made available to the registrant for comments. The options are:
- Acceptance of the testing proposal
- Acceptance of the testing proposal under modified conditions
- Acceptance or rejection of the testing proposal but requiring one or more additional tests
- Rejection of the testing proposal

iii) Decision-making

The draft decision, along with information provided by third parties, registrant comments and ECHA's responses to these comments, is submitted to ECHA's Member State Committee (MSC). ECHA can adopt the decision if the MSC unanimously agrees on the draft or on proposed amendments to the draft. If unanimous agreement is not reached, the decision is taken by the European Commission. Under the committee procedure [24] the Commission is assisted by the REACH Committee, made up of Member State representatives and chaired by the Commission. The chair circulates a draft decision on which the REACH Committee delivers an opinion by qualified majority. If the REACH Committee agrees with the draft, the Commission adopts the final decision.

iv) Follow-up

The decision sets out by when the registrant must deliver the required information in an updated registration file. Once this deadline has passed, ECHA checks whether the information has been provided or not. This can lead to different outcomes. For example, if the information has not been submitted or is inadequate, ECHA informs the relevant Member State and the registrant about non-compliance.

Member States are tasked with enforcing any infringements of REACH. Each Member State determines the penalties to apply, which must be effective, proportionate and dissuasive.

[1] [Prepojenie] The purpose of this glossary is to help the reader navigate the Ombudsman's decision. For the legally correct REACH definitions, the reader may wish to consult the ECHA-term tool: http://echa-term.echa.europa.eu/home [Prepojenie].

[2] [Prepojenie] Reproductive toxicity entails the potential impairment of male and female sexual function and fertility, harmful effects on the developing organism during pregnancy and post-birth, and effects on or via lactation.

[3] [Prepojenie] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals, OJ L 396, 30.12.2006, p. 1–849.

[4] [Prepojenie] For a more detailed description of how REACH works, please consult Annex I at the end of this decision.

[5] [Prepojenie] The letter opening the inquiry is available here: http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/64026/html.bookmark [Prepojenie].

[6] [Prepojenie] The Commission's reply is available here: http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/68996/html.bookmark [Prepojenie].

[7] [Prepojenie] The meeting report is available here: https://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/73277/html.bookmark

[8] [Prepojenie] The EOGRTS includes test packages or 'modules' that may or may not be put into operation, depending on the substance-specific circumstances. The basic one-generation study design to assess reproductive toxicity can be expanded by testing (i) a second generation for reproductive performance, (ii) developmental neurotoxicity and/or (iii) developmental immunotoxicity.

[9] [Prepojenie] The Ombudsman’s letter is available here: https://www.ombudsman.europa.eu/cases/correspondence.faces/en/81421/html.bookmark

[10] [Prepojenie] The meeting report is available here: https://www.ombudsman.europa.eu/cases/correspondence.faces/en/81422/html.bookmark

[11] [Prepojenie] The Commission’s detailed response is available here: https://www.ombudsman.europa.eu/cases/correspondence.faces/en/81423/html.bookmark

[12] [Prepojenie] Article 22(e) of REACH requires the registrant to update its registration where it *'identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal shall be developed'* .

[13] [Prepojenie] The reason for this change in timing, compared to the planning submitted in the initial reply to the Ombudsman, is that the Commission decided to revisit the cases and look at the updates made before September 2016 instead of January 2016. As such, its decisions

are based on the most up-to-date information received from registrants.

[14] [Prepojenie] According to ECHA, concerns about, and lack of information on, effects on reproduction were among the main arguments leading to REACH. See ECHA Report on the Operation of REACH and CLP 2016, June 2016. p.65.

[15] [Prepojenie] ECHA included the following action in its 2016 Work Programme: *"Re-assess testing proposals, approximately 200, submitted by registrants on reproduction toxicity and referred to the Commission for decision in years 2011-2014, which are anticipated to be re-submitted to ECHA due to the amendment of the REACH standard information requirements. These will need to be re-examined and concluded with draft decisions; cases will be grouped and prioritised with the aim of efficient and effective handling of them".* See ECHA Work Programme 2016, p.19.

[16] [Prepojenie] See the Commission's first reply to the Ombudsman, dated 27 June 2016: *"The* **delay** *in the adoption of the Commission decisions does not affect the placing on the market of the substances by the companies concerned… The* **delay** *is expected to have limited impact on human health."* (emphasis added by the Ombudsman)

[17] [Prepojenie] Judgment of the Court of Justice of 13 November 2014, *Nencini v Parliament* , C-447/13 P ECLI:EU:C:2014:2372, paragraph 48.

[18] [Prepojenie] See footnote 15 above which notes the fact that ECHA expected to be in a position to start dealing with the pending files in 2016.

[19] [Prepojenie] Before September 2016, 11 of the registrants with pending testing proposal decisions and 2 with pending compliance check decisions updated their proposal with an EOGRTS testing proposal.

[20] In response to the Commission's points on the usefulness of obtaining updates, set out in point 13 above, the Ombudsman notes that she did not misunderstand anything. As soon as the Commission has completed the ongoing procedure, ECHA should be able to advance in its work. In the Ombudsman's view, it should - ideally - not have to wait an additional 90 days for registrants to update their files in response to the Commission decision.

[21] [Prepojenie] See ECHA Report on the Operation of REACH and CLP 2016, June 2016. p.12.

[22] [Prepojenie] The Commission is conducting an evaluation of REACH, covering five criteria: effectiveness, efficiency, relevance, coherence and EU added value, including examining the potential to improve the way REACH delivers on its objectives. This should help identify where adjustments are necessary. Specifically, the Commission is currently preparing a Staff Working Document, presenting the results of the evaluation, as well as a general report on the

functioning of REACH.

[23] [Prepojenie] REACH is a lengthy piece of legislation and this explanation is not intended to be comprehensive. It is limited to certain aspects of REACH covered in the Ombudsman's decision and seeks to help the reader understand the relevant elements. As such, it does not cover all the legal and scientific complexities of the system. For a detailed explanation, please visit the section of ECHA's website devoted to REACH: https://echa.europa.eu/regulations/reach.

[24] [Prepojenie] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13-18.