

**Task Force on the
Workability of
Applications for
Authorisation**

March 8

2016

The Task Force on the Workability of Applications for Authorisation has concluded the first phase of its work on the simplification and streamlining of the application for authorisation process. This report outlines the activities undertaken in 2014-15 and proposes objectives for 2016-17 to further improve the functioning of the application for authorisation process.

**Report of activities
in 2014-15 and
objectives for work
for 2016-17**

Task Force on the Workability of Applications for Authorisation: Report of activities in 2014-15 and objectives for work for 2016-17

The Task Force on the Workability of Applications for Authorisation (task force) has concluded the first phase of its work on the simplification and streamlining of the application for authorisation process. This report outlines the activities undertaken in 2014-15 and proposes work objectives for 2016-17 to further improve the functioning of the application for authorisation process. This report and the objectives were discussed and agreed in CARACAL on 8 March 2016 with an addition of an objective on clarifying minimum information requirements for applications in Section B.

A. Report of activities in 2014-15

1. Background

The AfA task force was established following CARACAL-15 (8-9 July 2014), where the Commission proposed a way forward for a workable application for authorisation process. The proposal was based on feedback received from Member States, ECHA and the Commission through an online survey done from 14 April to 7 May 2014 (receiving 18 responses from Member States, one response from the Commission and one from ECHA) and at a workshop held in the Netherlands on 2-3 June 2014.

The purpose of the survey and the workshop was to identify difficulties in the implementation of the authorisation process and propose solutions to increase the predictability, efficiency and proportionality of the authorisation system. A number of specific cases were identified where the application for authorisation could be regarded as disproportionately costly compared to the likely risks from the Annex XIV substances when used, including uses of Annex XIV substances in low quantities, uses of Annex XIV substances to produce legacy spare parts for certain articles (for example aircraft and motor vehicles) where the substance is required for repairing an article that is no longer produced after the sunset date, as well as uses of Annex XIV substances as sources of biologically essential nutrients.

2. Objective

As an outcome of the survey, the conclusions at the workshop and the discussion in CARACAL, it was agreed to set up a task force with the overall objective of:

- Assisting on technical and practical aspects in the development of the streamlined application for authorisation approach for all cases in general; and
- Assisting on technical and practical aspects in the development of a possible "Authorisation implementing act" in selected special cases.

It was recognized that this work would require a coordinated effort of several involved parties. Consequently, the task force was established in August 2014 with representatives from the Commission, the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC), the ECHA Secretariat and a number of Member State Competent Authorities (MSCAs)¹.

3. Working method

The task force was established in August 2014 and has to date held a total of six face-to-face meetings and four WebEx meetings. The task force received notes and papers, prepared by its members, discussed these and gave their views to complete them. The names and affiliations of the experts participating in the task force meetings are given in Annex 1. The task force met also with stakeholders to discuss specific issues, such as legacy spare parts (with aviation and automotive industry) and the outcome of the workshop on 'process chemicals'.

The main focus of the task force during 2014-15 has been to support the development of the "special cases" for which the application for authorisation procedure could be simplified. The task force consulted stakeholders and provided input on what is needed at the decision-making, opinion-making and application stages.

In 2015, the objective of the task force was widened in its work plan to also include general streamlining activities with the aim of facilitating the application for authorisation process further. This has involved a reflection on support documents for applicants (see e.g. sections 4.2.2 and 4.2.3) and engaging with stakeholders to find out what could be done to further facilitate the application effort (see e.g. section 5).

4. Deliverables of the task force

The task force produced deliverables in two work areas:

1. Simplification of the application for authorisation process
2. General streamlining of the application for authorisation process

The activities and results of these two work areas are presented below. Some of the activities have been completed while others are still under consideration/development. These are described in the work plan for 2016.

4.1 Simplification of the application for authorisation process

A key deliverables of the Task force have been its contribution to the development of two of the special cases for which the general and full-scale application for authorisation process has been considered disproportionately costly. These were applications in relation to

1. Low quantities
2. Legacy spare parts

¹ Member State Competent Authorities currently represented in the task force are Belgium, Denmark, France, Germany, the Netherlands, Sweden and the United Kingdom.

The task force delivered the concept and the initial document formats on how applications for low quantities and legacy spare parts could be made. The Commission used these deliverables and held a public consultation from February to April 2015 on the simplification of the application for authorisation procedure concerning uses of substances in low volumes and on a one-time extension of transitional arrangements for uses of substances in legacy spare parts. The draft application formats for low quantities applications were included for information. In total 89 responses were given. The results were discussed in CARACAL in June 2015.²

The task force has discussed a potential special case for applications for authorisation concerning uses of Annex XIV substances as sources of 'biologically essential nutrients'. The task force has also considered a potential special case for uses requiring type approval/certification (such as for the production of motor vehicle parts). It considered that the type approval scheme, in itself, was not enough to justify a special case but would benefit from the general streamlining of applications for authorisation. All the special cases are outlined below in more detail.

4.1.1. Low quantities

Background: Many stakeholders considered the use of Annex XIV substances in very low quantities the clearest specific case for seeking streamlined and simplified solutions. This was mainly due to the disproportionality of the effort (and thus cost) of preparing a full-scale authorisation application in those cases compared with the potential risks related to continued use of these substances.

Outcome: As a result of the work of the task force the Commission plans to submit an Implementing Act in early 2016 to the REACH Committee with view of adoption in the spring of 2016. The Commission intends to propose that a low quantity application for authorisation may cover a maximum quantity of 100 kg per applicant per year for all uses and supplies and 100 kg per users from different supplies. The Act would exclude uses in mixtures for supply to the general public when the concentration in mixture is above the Article 56(6) limit and incorporation into articles for consumers/general public.

The task force's main contribution to this work has been to help defining the level of detail in the application for authorisation, including the development of simplified draft application formats and instructions, as well as the work required for the evaluation of the applications. The Implementing Act will mainly specify the details to be included in the analysis of alternatives and the socio-economic analysis.

4.1.2. Legacy spare parts

Background: The legacy spare parts special case refers to uses of Annex XIV substances in the production of spare parts intended for articles that have been placed on the market and whose production stopped or will stop before the sunset date. For articles with long life-spans, parts that meet the certain specifications need to be available and

² More information is available here: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081&lang=fr&title=REACH-Authorisation---Consultation-on-applications-for-low-volumes-and-on-extension-of-transitional-arrangements-for-uses-in-legacy-spare-parts-

may require specific materials and substances to be used. The possibility to substitute is expected to be limited, while the risks to human health or the environment from continued use in the substance is decreasing over time. It would be logistically and economically infeasible to produce all spare parts that may be needed in the future before the sunset date. Should legacy parts no longer be available after the sunset date, this could result in earlier disposal of the articles (e.g. airplanes or cars) for which they are intended.

Outcome: In early 2016 the Commission intends to propose a three year extension of the transitional arrangements (latest application dates and sunset dates) for uses of Annex XIV substances in legacy spare parts. The extension is an interim arrangement to avoid disruption in the supply of legacy spare parts during the development of a simplified application approach for legacy spare part uses (similar to the approach for low volumes).

Next to the proposal for legacy spare parts, the Commission is considering whether to address also the repair of legacy articles with Annex XIV substances and mixtures containing them. As to the maintenance, it is considered too difficult to define in general the operations and activities that this term should cover.

The actual application for authorisation for legacy spare parts was also discussed in the task force. A draft for an application format -- very similar to that of low quantities -- was discussed in a preliminary manner. The finalisation of this application format needs to be addressed in the second phase after clarification of the legal requirements for uses of Annex XIV substances in legacy spare parts.

4.1.3 Biologically essential nutrients

Background: The task force considered potential simplification/streamlining options for the use of substances of very high concern (SVHCs) as sources of biologically essential nutrients, in case the relevant substances are added to Annex XIV of REACH.

Outcome: ECHA, in collaboration with the task force, prepared a discussion paper summarising known uses of SVHCs as sources of biologically essential nutrients, including industrial fermentation (biotechnology), biogas production and wastewater treatment, and fertilisers (agriculture). Based on that discussion paper, the Commission submitted a policy paper for the November 2015 CARACAL meeting, outlining both legislative and non-legislative options to simplify or streamline the application procedure for these uses. Member States have submitted the comments on the paper. At the time of writing this report the Commission is considering how to proceed with this issue. Once this becomes clearer the task force could provide its advice on how a potential application for authorisation of essential nutrients would take place.

4.1.4. Type approval/certification scheme

Background: The task force discussed with the aviation and automotive industry sectors whether a 'special case' would be warranted for the production of parts subject to type approval/certification schemes. The aviation industry highlighted that one of its main difficulties was the lack of knowledge on the part of original equipment manufacturers on which substances their suppliers used in the parts. This was due to the widespread use of "functional specifications" and uncertainty related to whether suppliers using Annex XIV substances would apply for authorisation. The task force recognised that this

difficulty was real, but that it first and foremost related to supply chain management. In some cases 'low quantities' approach could help, though. The automotive industry mainly highlighted issues around the production of legacy spare parts, which would be addressed by the legacy spare parts special case subsequently developed by the task force.

Outcome: The existence of a type approval/certification scheme may well be an important factor to be taken into account in the analysis of alternatives. Thus, the task force considered that this should be demonstrated in an appropriate and streamlined manner in a normal application for authorisation. The task force noted that in some cases the certification requirement could justify long(er) review period. It concluded that this was not, in itself, an argument for a special case.

4.2. General streamlining of the application for authorisation process

In addition to the simplification efforts described above, the task force has considered more general solutions to further facilitate and streamline the application for authorisation process.

4.2.1 Process chemicals

Background: In response to feedback from industry, the task force considered whether it was possible to streamline the application for authorisation process for industrial "process chemicals". In general, a process chemical can be defined as a chemical that provides a particular function in a given process but which is not aimed at being present in the end-product. According to industry, many process chemicals are used in industrial settings in a highly controlled manner and are not present in final products. In such cases industry asserted that the human health or environmental impact of the use of the substance would be low.

Outcome: Based on a discussion paper prepared by ECHA the task force considered that - from an exposure and risk perspective -- use as an industrial process chemical does not, in itself, imply necessarily that the human health or environmental impact is low. In terms of risk, such uses may be of concern due to high volumes used and the need for recovery and regeneration (resulting in fugitive emissions). Consequently, the task force concluded that it is not possible to develop a special case for 'process chemicals'. However, the task force considered that common and standardised elements of applications from within specific sectors (e.g. the pharmaceutical industry, which has strict approval process) could be used as part of a conventional application.

The task force also considered what support could be given to applications for uses with low impact on human health and the environment, especially for streamlining the application in case of low risk. This issue was raised both at the Process Chemicals Workshop on 23 September 2015 and the Workshop on Streamlining Applications for Authorisation on 17 November 2015. The task force intends to work further on this in the second phase of its work.

4.2.2 Examples of analyses of alternatives and socio-economic analyses

Background: The task force discussed the need to have practical examples of applications for authorisation so that future applicants could see how to approach these issues in their own applications. The task force recognised the difficulty of itself preparing such examples.

Outcome: Based on the discussions in the task force ECHA has published a set of examples from past applications that are illustrative in terms of the clarity of reporting, the coverage of the key issues as well as the extent to which the analyses are evidence-based and referenced. The intention is to update the list periodically with the aim of having a good coverage of examples relevant to applications for authorisation.³

An area for further work will be to outline the experience of RAC and SEAC in evaluating the applications. In early 2016, ECHA intends to publish checklists and the “opinion trees” for the evaluation of applications for authorisation in RAC and SEAC. Later in 2016, the task force also intends to provide input into a practical ECHA guide to applicants, which will be partly based on feedback from the Committees, past applicants, and stakeholders.

4.3.3 Readers’ guide for preparing an application for authorisation

Background: The task force noted that applicants were not always aware of all the available material related to applications for authorisation (guidance documents, instructions, Q&As etc.). One reason for this was that the information is spread out over several different sections in ECHA.

Outcome: To quickly address this issue, the task force thought that the publication of a ‘Readers’ guide’ to applications for authorisation would be helpful. The guide provides potential applicants, and their advisors, an overview of the key information to read before preparing and submitting an application for authorisation, including information on how applications are assessed by RAC and SEAC. The guide will be updated based on feedback of applicants and stakeholders as well as the publication of new documents.⁴

4.3.4 Recycled materials containing SVHCs

Background: The task force also considered a possible streamlining/simplification proposal developed by the Austrian MSCA for uses of recycled materials containing Annex XIV SVHCs. The proposal involved recyclers associations applying for downstream uses in parallel with a Commission decision establishing a type approval authorisation for the placing on the market and the use of recycled materials containing Annex XIV substance.

Outcome: While many task force members saw benefits in the approach, it acknowledged important legal constraints. Instead of introducing a new type approval

³ See <http://echa.europa.eu/support/socio-economic-analysis-in-reach/examples-of-sea-and-analyses-of-alternatives>

⁴ The readers’ guide can be viewed here: http://echa.europa.eu/documents/10162/13566/readers_guide_en.pdf

approach, the task force concluded that ECHA could work with the recycling industry to help companies organise themselves for the applications.

4.3.5 Upstream applications for authorisation

Background: The task force considered how to best and most effectively fulfil the information requirements for upstream applications for authorisation (i.e. submitted by manufacturers, importers or only representatives). This was also a key focus of the Workshop on Streamlining Applications for Authorisation on 17 November. A conclusion of this workshop was that upstream applications are essential for the workability of the application process. At the same time, there are important challenges that need to be addressed.

Outcome: The task force has identified specific issues related to upstream applications. These comprise use description and the scope of uses. These are at least partly addressed by the update of the technical guidance on use descriptions that ECHA will do in early 2016,

The task force will need to focus its work on feasibility of alternatives, representativeness and identification of non-use scenario. In the second phase of its work, as well as on communicating the outcomes on these issues to public and future potential applicants.

5. Events

The task force helped the Commission and ECHA in organising two events that have informed the work on improving the functioning of the application process:

1. Conference on Lessons Learnt on Applications for Authorisation, Helsinki, 10-11 February 2015⁵

The purpose of the conference was to get feedback on the functioning of the application for authorisation process from past, present and future applicants, MSCAs, the Commission, ECHA, including RAC and SEAC, as well as other stakeholders. It was established that the application process is working and areas for further improvement were outlined. The conference was attended by 130 representatives from industry, authorities and NGOs.

2. Workshop on Streamlining Applications for Authorisation, Brussels, 17 November 2015⁶

The workshop was a follow-up to the conference held in February. The aim was to further improve the functioning of the application for authorisation process under the REACH Regulation by focusing on two aspects: how to make 'fit-for-purpose'

⁵ The presentations and conclusions of the conference are available at http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation

⁶ The presentations and conclusions of the conference are available at http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/workshop-on-streamlining-applications-for-authorisation

applications in general and how to best and most effectively fulfil the information requirements for 'upstream' applications. The workshop was attended by 100 representatives from industry, authorities and NGOs.

Furthermore, some task force members contributed to the Process Chemicals Workshop, which was organised by Cefic and Eurometaux, in association with the German Federal Institute for Occupational Safety and Health (BAuA) and ECHA, in Brussels on 23 September 2015⁷. The workshop was attended by approximately 50 industry representatives from various sectors, as well as approximately 10 representatives from ECHA, the Commission and MSCAs. Some task force members also contributed to a workshop on applications for authorisation held on 27 April 2015 in Germany⁸.

6. Assessment

Looking back at the work undertaken by the task force in 2014-15, there are several areas that have worked well:

- The task force proved to be a good forum to solicit the views of main parties (Commission, Member States and ECHA – including its committees) on technical and practical aspects.
- The task force strived to identify issues in a systematic way. It gave advice quickly and efficiently in 2014 and early 2015 to resolve issues related to low quantities and legacy spare parts. This was fed as an input into the preparation of a Commission proposal for the Draft Implementing Act on Authorisation which should be adopted soon.
- The task force worked in an inclusive way, involving a range of different stakeholders. It met with specific stakeholder groups (legacy spare parts), held specific meetings (process chemicals) and helped in organising the major stakeholder events.
- The task force worked in a flexible, informal and lean manner. Meetings were held on an 'as needed' basis and often back-to-back to other meetings. Thus, despite relatively small resources, the task force was able to add value.
- The task force was able to give advice on practical improvements with clear deliverables.

In hindsight, given that the application for authorisation is a new process, the task force identified issues that could have worked better and that should be considered in the possible next phase of the task force:

- The resources of the task force were limited and the workload could have been distributed more evenly.
- While it was able to identify upstream applications as a challenge, the task force did not give specific advice on how to tackle this. This work would require further

⁷ See <http://www.cefic.org/newsroom/Events/Past/September-23-Workshop-Applications-for-authorisation-for-Process-Chemical-uses-ensuring-fit-for-purpose-applications/>

⁸ <http://www.reach-clp-biozid-helpdesk.de/de/Veranstaltungen/2015/Veranstaltungen15-0427.html>

involvement of all parties. The task force intends to focus more on it in the second phase of its work.

- Due to the novelty of the process and relatively few staff resources available, the remit of the task force was not always clear relating to what were considered policy issues at decision making and what would be considered to be technical issues relating to ECHA's committees.
- While the task force strived to work in an open and inclusive manner, it could have better communicated about its work in particular to the stakeholders. The task force intends to further consider how to clearly communicate about its activities in the second phase of its work.

B. Objectives for 2016-17

The initial objectives have been mainly reached in 2015 but the task force can be helpful in following through their implementation. There is also a need to further work on improving the functioning of the application for authorisation process. As an overall objective, the task force identifies specific problems in the application for authorisation opinion-making process and proposes solutions, taking into account the needs of the decision-making process.

The second phase of the task force's work would comprise the following specific objectives:

- 1) **Finish off current business:** Have supported ECHA and the Commission during the implementation of a simplified application for authorisation process for low quantities and legacy spare parts (including the application formats), as well as provided input on the update of the technical guidance on use descriptions. This is planned to be completed by mid-2016 for low quantities and later for the legacy spare parts.
- 2) **Streamlining, including a practical guide:** Have provided advice to ECHA's practical guide to applicants. This guide aims to clarify and streamline the application process for all applicants. Specifically it should include separate sections on 'low impact' and 'upstream' applications. It will be partly based on feedback to be collected from past applicants and stakeholders in the spring of 2016 regarding what the guide should cover, as well as on presentations given by participants to the workshops, including the experience from the Committees' work in evaluating the applications for authorisations presented in those workshops. The finalisation of the guide depends partly on the comments received from stakeholders. The aim is to finalise it as soon as possible and in any case by the end of 2016.
- 3) **Minimum information requirements:** Have given advice to ECHA on the clarification of minimum information requirements for applications in relation to conformity.
- 4) **Review phase of authorisation:** Have assisted ECHA and the Commission in the development of ECHA's guidelines on what authorisation holders should include in the review reports and how ECHA's committees give opinions on them. The aim is to have the guidelines ready in early 2017, at the latest.

- 5) **Stock-taking conference:** Have assisted the Commission and ECHA to organise an “Application for authorisation stock-taking” conference after the majority of the decisions of chromates have been issued and first experiences with the enforcement of authorisations gained. It is likely to take place once the opinion making phase of the current wave of applications will have ended (second half of 2017).

The task force will prepare a work plan once the objectives have been confirmed. The task force will communicate clearly, as pertinent, about its work and give advice on how the above can be communicated in an appropriate manner. For example, it will contact past applicants and stakeholders and ask them to provide input to the practical guide.

The objectives will be adapted depending on possible new issues that may arise from the opinion-development or decision-making related to the applications for authorisation.

Task force Members

The following have participated in the Task Force meetings:

European Commission

Manol Bengyuzov (DG GROW)
 Valentina Bertato (DG GROW)
 Sylvain Bintein (DG ENV)
 Anna Borrás-Herrero (DG GROW)
 Carolina Ceijas Noguera (DG ENV)
 Cristina De Avila (DG ENV)
 Mateo Gallego (DG ENV)
 Enrique Garcia John (DG GROW)
 Giuseppina Luvara' (DG GROW)
 Katarina Pirselova (DG ENV)
 Wim Riepma (DG GROW)

European Chemicals Agency

Jean-Marc Brignon (SEAC member)
 Lina Dunauskienė (RAC member)
 Stavros Georgiou (SEAC member)
 Betty Hakkert (RAC member)
 Philipp Hennig (Risk Management
 Implementation Unit, up to July 2015)
 Sanna Henrichson (Risk Management
 Implementation Unit, from July 2015)
 Thierry Nicot (Risk Management
 Implementation Unit)
 Urs Schlüter (RAC member)
 Peter Simpson (Risk Management
 Implementation Unit)
 Matti Vainio (Risk Management
 Implementation Unit)
 Tomas Öberg (SEAC chair)

Member States

Belgium (Federal Public Service of
 Health, Food Chain Safety and
 Environment):

Catheline Dantinne
 Gwennaëlle Maes
 Martine Rohl

Denmark (EPA):

Bent Horn Andersen (up to July 2015)
 Finn Pedersen (from July 2015)

France (Ministry of Sustainable
 Development):

Sylvie Drugeon
 Wodli Jordane

Germany (Federal Institute for
 Occupational Safety and Health):

Ann Bambauer
 Kerstin Heesche-Wagner
 Aart Rouw
 Thea Hammerschmidt (- October 2015)
 Philipp Hennig (September 2015 -)

The Netherlands:

Jan Wijmenga (Ministry of Environment)
 Richard Luit (Dutch National Institute for
 Public Health and the Environment)

Sweden (Chemicals Agency):

Lars Gustavsson
 Anne-Marie Vass

UK (Health and Safety Executive):

Gary Dougherty

Task force-related documents

The task force discussed and gave advice on the following:

1. Follow-up to NL Workshop: Development of a streamlined Application procedure for special cases (CARACAL-15, 8-9 July 2014) (Doc. CACS/32/2014)
2. Way forward for a workable Authorisation process (CARACAL-15, 8-9 July 2014) (Doc. CACS/29/2014)
3. Organisation of Task Force for improving the workability of the AfA process (25 August 2014)
4. Special cases – Authorisation (12 November 2014) (the Commission)
5. Yes – to simplified AfA for low tonnage; No – to neglecting the diversity of risk (14 November 2015) (German MSCA)
6. The EU type-approval framework for new vehicles (12 January 2015) (the Commission)
7. Challenges for automotive industry and possible solutions - Spare parts under Authorisation (12 January 2015) (ACEA and CLEPA)
8. Task force briefing – Aviation and authorisation (12 January 2015) (ASD)
9. Certification process (12 January 2015) (EASA)
10. ECHA internal efficiency programme for AfA (12 January 2015)
11. Public consultation on: simplification of authorisation procedure for low volumes; and uses of Annex XIV substances in legacy spare parts (12-13 January 2015) (the Commission)
12. Formats (CSR, AoA and SEA) for low quantity and legacy spare part applications (several versions, latest in February 2015)
13. From “bare necessities” to a standardized AfA (25 March 2015) (German MSCA)
14. A “Thought Starter” for a standardized Application for Authorisation for process solvents (25 March 2015) (German MSCA)
15. First thoughts on process chemicals (26 March 2015) (ECHA)
16. Process chemicals in applications for authorisation - first thoughts and next steps (10 June 2015) (ECHA)
17. Thought starter on the implementation of the authorisation process (CARACAL-18, 23 – 24 June 2015) (Doc. CA/MS/60/2015, submitted by Swedish CA)
18. Authorisation of uses of recycled materials under REACH - proposal for a type approval approach (31 August 2015) (Austrian MSCA)
19. Task force work plan until the end of 2015 (16 September 2015)
20. Applications for Authorisation for “process chemical” uses - A report from the workshop (24 September 2015) (Cefic)
21. Biologically essential nutrients in AfA: Potentially relevant uses and suitable simplification approaches (11 November 2015) (ECHA)

As a result of the work of the task force, the following were produced:

1. Streamlining and simplifications of the authorisation process (CARACAL-17, 26 – 27 March 2015) (Doc. CA/16/2015)
2. Results of the public consultation on applications for low volumes and on extension of transitional arrangements for uses in legacy spare parts and proposed follow-up, including formats for simplified AfA (CARACAL-18, 23 – 24 June 2015) (Doc. CA/50/2015)
3. Authorisation for uses as sources of essential nutrients (CARACAL-19, 12 – 13 November 2015) (Doc. CA/82/2015 rev.1)
4. A total of 27 presentations given at the Conference on Lessons Learnt on Applications for Authorisation on 10-11 February 2015 and at the Workshop on Streamlining Applications for Authorisation on 17 November 2015
5. Examples of analyses of alternatives and socio-economic analyses (published in November 2015)
6. The readers' guide to preparing an application for authorisation (3 December 2015)