**Helsinki, 21 June 2011**

**Doc: MB/32/2011 final**

# Report from the Chairman of the Board of Appeal

**(Document submitted to the Management Board)**

**PROGRESS REPORT OF THE BOARD OF APPEAL**
**21-22/JUNE/2011**
**(Supporting Document)**

## 1.Introduction

This document provides the members of the Management Board (MB) with additional and supporting information to the presentation to be given by the Chairman of the Board of Appeal (BoA) at the meeting on 22 June 2011.

### *News in the Board since the last presentation at the Management Board in December 2010*

Since the last update by the BoA to the Management Board in December 2010, some important changes have occurred in the BoA's composition and also in the Management Working Group for the Board of Appeal.

Firstly, the Technically Qualified Member, Harry Spaas , retired and was replaced by Andrew Fasey (summary CV attached as Annex 1 to this document).

Likewise, in the last Management Board (MB) meeting of January 2011, one of the three members of the Management Board Working Group for the Board of Appeal, Katarzyna Kitajewska, was replaced by Jan Karel Kwisthout. He now joins Ana Fresno and Gustaaf Bordchardt as the MB Working Group (MB WG) with responsibility for BoA issues on behalf of the Management Board.

The annual appraisal of the BoA members (Mercedes Ortuño, Chairman; and Mia Pakarinen, Legally Qualified Member) was carried out by the MBWG during a meeting in Helsinki, on 5 May. The members of the MBWG act as reporting officers for the BoA members. The objectives of the BoA members for 2011 were also agreed.

## *2.The Appeal Process*

### *Description of the appeal process*

The basic elements of the appeal procedure are mentioned in REACH (for example, which decisions are appealable, who is entitled to appeal, admissibility of appeals, consultation and rectification, the effects of an appeal on the contested decision etc); but a more complete description of the procedure is included in the Rules of Organization and Procedure of the BoA (Regulation 771/2008).

Additionally, a quality document which describes the complete appeal procedure is being developed. It will include a detailed description of the activities to be performed by the BoA members and the Registry.

A basic description highlighting the main steps in the process has been included in the slides of the presentation; a more detailed flow-chart is provided in Annex 2 to give the MB a more complete description of the work process to be followed by the BoA in making its decisions .

Once the quality document is finalised, it will be a useful tool not only for the regular actors involved in the appeal process but also for the alternate and additional members (AAMs), who are less frequently engaged in cases.

***3.Cases filed to date***

***Note:*** *information on appeals is available on line; in the appeals section of the ECHA web site (see http://echa.europa.eu/appeals_en.asp).*

***Appeal A-001-2010***

***Rejection of Registration***

In December 2010, a new appeal was lodged. This case relates to an ECHA decision rejecting the registration because of the late payment of the registration fee. The decision also stated that the fee paid would not be reimbursed.

The appellant argues that the Agency's decision not to reimburse the registration fee paid was unfair. They claimed that it was due to the lack of clarity of the on-line information that the appellant did not pay the registration fee before the extended due date.

The appellant also states that due to this rejection they had to re-register and to pay the registration fee for a second time. According to the appellant, as a consequence of this payment the Agency received the fee twice for only one registration..

***Engagement of an Alternate Member***

It is important to note that in this case, which had to be allocated before the new member took over his position as Technically Qualified Member, an alternate member was called upon to work on the case. The systems for working together with a non-regular BoA member has been experienced (ex-change of documents, multi-conferences, timing and communication in general), for the first time.

The case is still pending.

***Appeals***

In February 2011 two similar appeals were submitted by two subsidiaries of the same company. In both cases, the

***A-001-2011 & A-002-2011***

***Rejections of Registration***

contested decision rejected the registration because an incomplete dossier was submitted; the reason being the failure by the appellant to include estimated production volumes

The appellants claimed that details of the manufacturing summary, production year and tonnage were provided. However, they stated that this information was considered as being commercially sensitive information and on that basis marked as being confidential business information. The appellants also argued that the information contained in the first rejection notice received did not contain sufficient information to correctly identify and consequently solve the problem.

In those two cases, no confidentiality requests were made.

Finally, after having consulted the Chairman of the Board of Appeal on the admissibility of these appeals, the Executive Director decided to rectify the contested decisions. The rectification implied that the registrations were accepted, the appeals were withdrawn, and both cases were closed.

***A-003-2011***

***Data Sharing dispute***

In February 2011 a new appeal was lodged by the lead registrant of a substance. This appeal was against a decision of the Agency granting a third company permission to refer to vertebrate animal studies contained in the joint registration dossier. According to the Agency's decision, the appellant had failed to make "every effort" to ensure that costs were shared in a fair, transparent and non-discriminatory way.

A confidentiality request was made by the appellant, which the Chairman accepted in part.

The appellant has withdrawn the appeal, on 19.5.2011, and the case has been closed.

***A-004-2011***

***Rejection of Registration***

In April 2011 an appeal was filed against a decision of the Agency rejecting the appellant's registration on the grounds that the fee payment had not been received by the deadline set.

The appellant claimed that it had made its submission successfully and had fulfilled all the relevant obligations. It adds, however, that due to an internal error the necessary fee was paid 26 days too late.

The appellant contends that the rejection of its registration with the corresponding fee not being refunded together with

the resulting obligation to make a new submission and pay the registration fee again is disproportionate and “out of scale”.

A confidentiality request was made by the appellant which the Chairman accepted in part.

The case is pending and waiting for further submissions.

***4.Maintenance and Improvement of BoA Expertise***

It is the responsibility of the BoA to make timely and well reasoned decisions, from the legal and technical/scientific point of view. It is therefore essential for the BoA to have an in-depth understanding of REACH processes and ECHA working methods.

***Training within ECHA***

In this respect, the training received from the ECHA operational units to date has been crucial. In particular, the training on registration, data sharing and evaluation provided by the responsible units has been of great help to better understand the processes followed by ECHA to perform these operations and, at the same time, it also helped the BoA to envisage where problems or difficulties could arise. More of such training is required on other aspects of REACH as well as regular update sessions. In addition it is important that the BoA has regular and ready access to other meetings within ECHA and its various Committees; This issue is addressed in the document [MB/33/2011] which is also on the agenda of this MB meeting.

***Internal training***

It has also been very useful to follow the internal training provided by the Technically Qualified Member and the Scientific Adviser, a member of the Registry Staff, on more practical and technical/scientific issues such as the functioning of SIEFs in practice and aspects of the evaluation process.

***Workshops & Conferences***

It is also necessary for the BoA to be in contact with and understand the ‘stakeholder environment’. In this respect the BoA members have participated in selected workshops and conferences , such as a conference on European Chemicals Policy ; CEFIC workshops, University forums etc. It is important that contacts are made with a range of stakeholders and steps are being taken to try to ensure that this is the case.

***Legal and Technical Research***

One of the key elements for BoA’s performance is to have in place a suitable knowledge management system, adapted to its needs. In this field the BoA develops legal and technical research on different issues of special interest, such as:

admissibility problems, confidentiality requests, time limits, data sharing, etc. The creation of a data base of research works and the collection and storage of useful materials will facilitate the consideration of future appeals

***5.BoA's Operability***

Much has been done over the last year or so to ensure that the Board can operate as effectively and efficiently as possible in anticipation of a much greater workload in 2011. In terms of staffing, the BoA is at full strength with the new Technically Qualified Member, Andrew Fasey, taking up his post from 1 March 2011 following the retirement of Harry Spaas in 2010. The Board and the Registry have prepared many work instructions (there are a large number of different actions and permutations that need to be considered) and formats (e.g. for communications from appellants, between the Board and the Registry, and between the Registry and ECHA) to help ensure that the appeals process works smoothly and efficiently. This work is on-going and revisions may be needed once a greater number of appeals have been processed and more experience is gained with the systems and approaches developed so far.

***Interaction with Alternate/ Additional members***

More Additional and Alternate Members (AAMs) have also been appointed. The AAMs can be called upon to be a member of a Board of Appeal for a specific case if one of the permanent members of the BoA is unavailable (e.g. absence, conflict of interest, workload). Rules have been established for the appointment of AAMs to particular cases and a Code of Conduct has been prepared and circulated to all AAMs. These aspects are particularly important for the AAMs , in order to identify and avoid potential conflicts of interests. This is an aspect that needs to be kept under constant review. In addition, there is a requirement for updating annually the declaration of interests.

One of the AAMs was designated as the technically qualified member of the Board for case A-001-2010. This was necessary during the period in-between the retirement of the previous Technically Qualified Member of the Board of Appeal and the appointment of the new one.

Once a year, a meeting is held with all the AAMs for training and information purposes. In addition, a CIRCA site has been set-up for the secure exchange of information relating to the appeals process. The BoA is further examining how to keep the AAMs better informed and create a 'learning environment', whilst ensuring the protection of confidential business information and the secrecy of deliberations, so that they can benefit from the experiences of the full-time members and the Registry.

## 6. Relations with ECHA's Secretariat

### The Administrative Arrangements of June 2009

The purely administrative relations between the BoA and ECHA Secretariat are set-out in a document signed by the Executive Director and the Chairman of the Board of Appeal in June 2009. This document, which was also explained to the Management Board at the time, only covers the daily evolvement within the same administrative entity, with the aim of guaranteeing BoA's independence. But there are some substantial aspects, such as the participation in ECHA's Committees and the Forum, or the access to ECHA expertise, which are not foreseen in these arrangements.

### Understanding on ECHA's processes

Whilst the BoA has a strong relationship with the ECHA Secretariat there is an underlying tension related to the need for the BoA to remain, and to be seen to be, impartial and independent. A lot of work continues to be carried out to see how the links between the BoA and the work and processes of ECHA can be strengthened whilst maintaining this impartiality and independence. A document MB/33/2011, addressing this issue, is on the agenda of this meeting.

### BoA involvement in ECHA's Committees and work

After a joint reflection by the ECHA secretariat and BoA, it was concluded that the participation of BoA in Committee meetings should be selective. An agreed starting point was that the BoA should not be present for any discussions on decisions or debates on specific cases.

It is important for BoA to obtain a clear understanding of how the Committees operate and to have direct and complete information on relevant scientific and technical discussions (e.g. risk characterisation). Such an understanding and information can only be obtained by observing appropriate parts of Committee meetings and the Forum. This will enhance the decision making capabilities of BoA without interfering with its impartiality and objectivity when deciding on cases. Attending such meetings will also add to the knowledge and expertise of BoA. The approach being taken now is a cautious one but with time and experience it will hopefully be possible to allow easier access for the BoA to Committee meetings without prejudicing BoA's independence.

Another important issue also tackled in the paper MB/33/2011 is the BoA's access to ECHA experts, and how ECHA expertise can be made available without threatening BoA's impartiality and independence

## 7. Challenges

There are many challenges facing the Board of Appeal, some of which are linked to the fact that this is a new activity both as

part of REACH but also in an EU Agency. Some of these challenges will be resolved as more experience is gained with real cases, others are perhaps more fundamental.

***Understanding stakeholder's environment***

Much of the last year was taken up with putting the systems in place for the Board to do its work. Whilst this work is not yet completed much has been done. It is therefore now important for the BoA to be as equipped as possible with the knowledge to do its job. This requires greater exposure to, and understanding of, the 'stakeholder environment'. The BoA needs to know what issues and problems stakeholders are facing in order to do their job whether as a registrant, a service provider, an NGO, a Member State, or ECHA. To this end, BoA members and the Registry will increasingly attend meetings, conferences, workshops etc on issues that may be related to future appeal cases. Such participation should also enable the Board to better inform stakeholders about the appeals process itself so that they know what they can expect if this is an approach that they decide to take.

***How to find good independent experts and maintain expertise***

It should be noted that the Rules of Procedure allow experts to be heard as expert witness, in the course of a case handling. The identification of suitable experts for this role is an important and difficult task.

A more general issue discussed in '*Relations with ECHA's Secretariat*' above, is how the BoA gains access to the experts and expertise it will undoubtedly need in the future. Many future appeals will be against ECHA decisions made under the evaluation process (e.g. testing proposals, compliance checks, and substance evaluation) and these are likely to be far more technical/scientific in nature than hitherto. The BoA cannot maintain the experts and expertise in-house to cover all the possible issues that may arise. The BoA will therefore need to have access to experts and expertise from elsewhere.

One of the solutions proposed in the background paper MB/33/2011, to regularly seek contacts with ECHA experts to discuss technical and scientific issues which do not concern any concrete case, is a helpful step forward.

The BoA will also need to consider whether experts and expertise should also be sought from the Member States, the ECHA Committees, service providers and other stakeholders and, if so, how such arrangements might be managed. This will be a major challenge as and when the appeals workload increases and appeals are related to increasingly complicate technical and scientific issues.

Furthermore, in order for the Board to produce high quality decisions as efficiently and effectively as possible, it also needs to maintain and improve the levels of expertise both within BoA and also in the Registry. To this end the Board has a need for training and updating on ECHA processes, to be kept informed of key developments within ECHA's competence, as well as having an in-depth understanding on the technical and legal matters under its competence. As mentioned above, there is some general training provided by ECHA and for the future it would be needed in a more selective and regular manner.

***Future workload, difficult to predict***

The BoA's future workload is certainly hard to predict. To date, far fewer appeals have been received than expected and most of these have been rectified by ECHA or withdrawn at a later stage. The number and timing of appeals will be linked to the various deadlines (e.g. registration, time limits for appeals, evaluation progress within ECHA) and the number and importance of ECHA's decisions. The number of negative decisions from ECHA on registrations has been less than expected perhaps because of the efforts made by ECHA, Member States and others to help registrants (e.g. the technical completeness check tool, the ECHA and Member State helpdesks, the work of the Directors Contact Group). Negative decisions however continue to be made and these may give rise to appeals. It can reasonably be expected that evaluations (e.g. testing proposals and compliance checks) following the first registration deadline will lead to a number of negative decisions some of which may subsequently be appealed.

It is hoped that discussions with stakeholders will lead to a better understanding of the 'stakeholder environment' which should in turn help the BoA to better predict the numbers and subjects of appeals.

***The next registration deadline***

Looking forward, many smaller companies will be preparing for the 2013 registration deadline. These companies may have fewer resources, less experience of regulatory chemicals issues and REACH in particular, and more data gaps for the substances subject to registration. This may well result in more data-sharing disputes as well as a greater number of questions on the compliance of registration dossiers, generating appeal cases in the future.

***Playing a Pioneer Role***

One of the key challenges of the Board of Appeal is related to the *pioneer role* of the BoA as a quasi-judicial body interpreting legal texts related to the REACH procedures. The Board of Appeal will be the first (quasi-judicial) body with responsibility for deciding on the correct interpretation of

relevant rules and concepts related to ECHA decisions.

This is a very challenging task, as the majority of the *concepts* related to REACH did not even exist in the legislation or in trade practice before REACH - neither as legal concepts nor as (settled) common activities of the chemical industry. For example concepts like SIEF, lead registrant, joint submission, opting out, third party representative, etc. are all new features. The same novelty also applies to majority of legal issues, which may arise in relation to the ECHA decisions. For the Board of Appeal this means in practice that there are few precedents to follow, and few clear similarities with other legal systems.

Attachments:

ANNEX 1 Summary CV of Mr Andrew FASEY
ANNEX 2 Flow-chart of the Appeal Procedure

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**Annex 1**

**Summary CV of Mr Andrew FASEY**

**Andrew Fasey**

Andrew Fasey has been working in the field of international regulatory chemical issues for over 25 years, approaching the complex issues involved from a number of different stand-points; occupational (working for the UK's Health and Safety Executive (HSE)), environmental (working for Directorate-General (DG) Environment (ENV) of the European Commission), industry (as a consultant primarily to industry for 7 years on REACH and CLP/GHS implementation), national (UK), EU (European Commission) and international (as a member of various OECD task forces). He has been intimately involved in two of the major international developments in internationals chemicals management of the last 15 years, namely the REACH Regulation and the Globally Harmonised System for the classification and labelling of chemicals (GHS).

Andrew was a member of the REACH Unit in DG Enterprise (ENTR) that drafted the European Commission's proposal for REACH and as a consultant, after leaving the Commission, he was Special Advisor on REACH to the Government of Finland during their Presidency of the EU at the end of which the REACH Regulation was finally adopted. He has been working as part of UK Government, the European Commission, and as a consultant to stakeholders (primarily, but not only, industry) on REACH for over 11 years.

Whilst working for the UK Government Andrew was a member of the IOMC (Inter-Organisational programme for the sound Management of Chemical) group that drafted the GHS. He was also a member of the OECD and ILO groups that developed much of the scientific and technical material that formed the basis of the GHS. He has represented the UK Government and the European Commission at meetings of the United Nations Sub-Committee of Experts on the GHS (UNSCEGHS) and was appointed as a Senior Special Fellow to, and subsequently a Training Advisor for, the United Nations Institute for Training and Research (UNITAR) to help in GHS capacity building projects around the world.

He has a degree in Civil and Environmental Engineering from the University of Newcastle-upon-Tyne and a Masters from the Imperial College (London University). He is a well known presenter and Chair at REACH and CLP/GHS conferences around the world and has written a large number of articles on REACH and CLP/GHS and is the joint author of a book on CLP.

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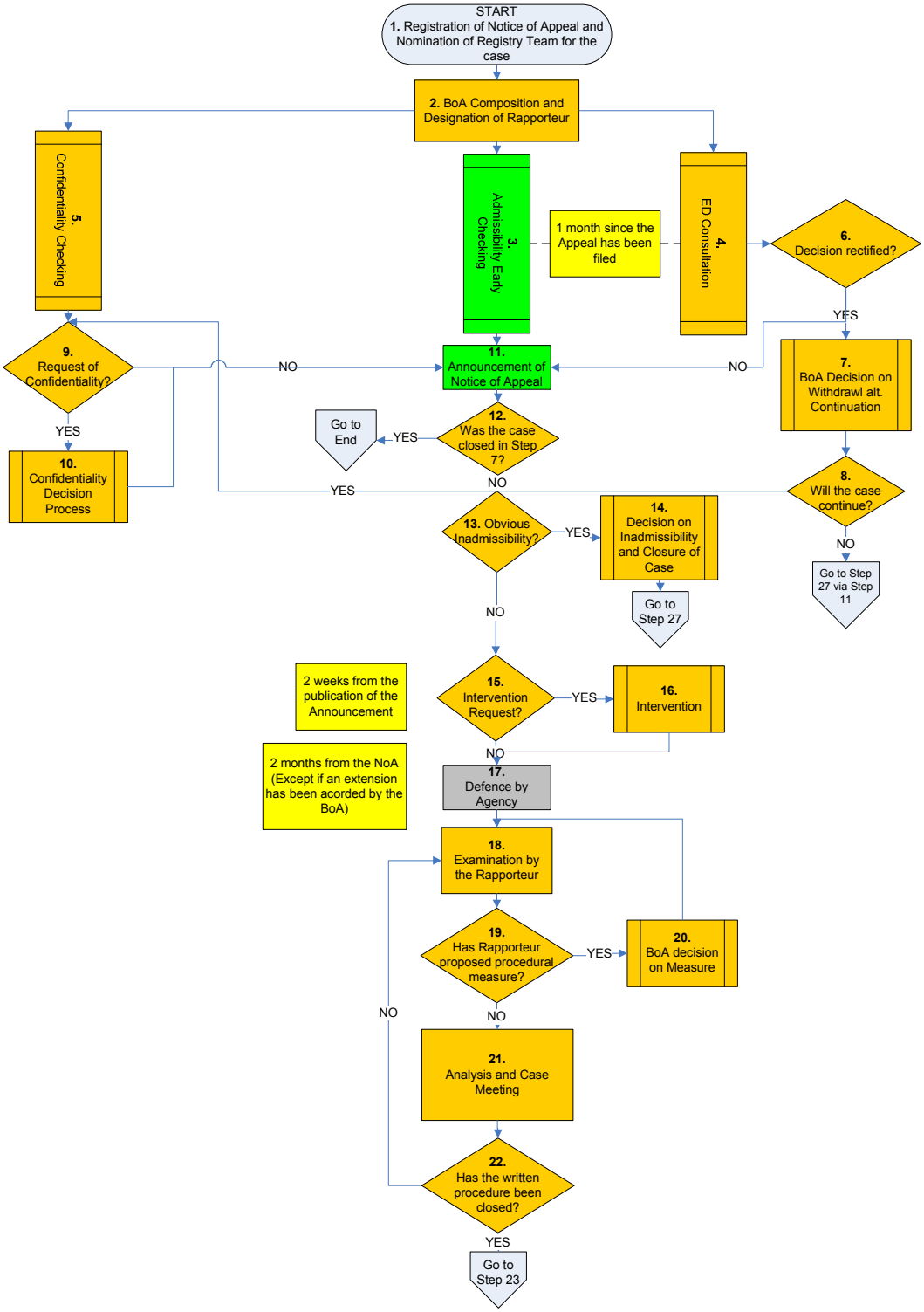
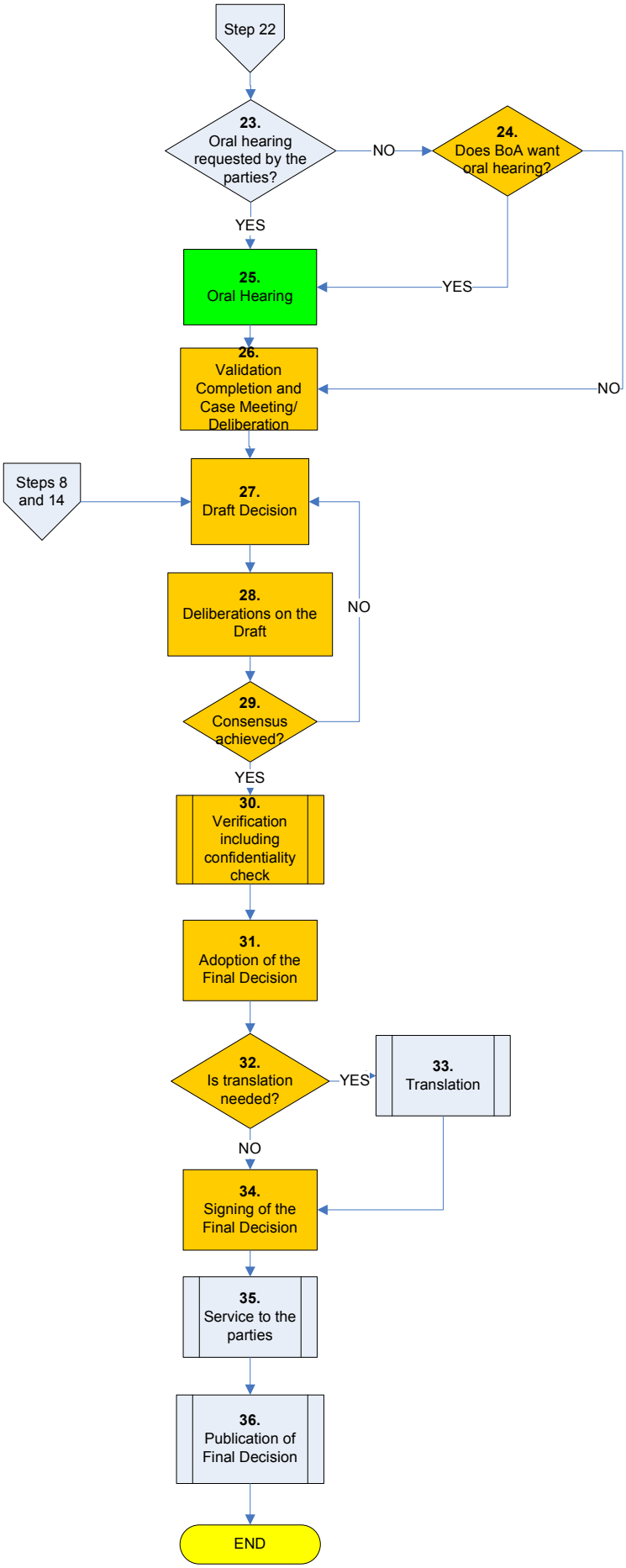
**Annex 2**




Step 22
23. Oral hearing requested by the parties?
NO
24. Does BoA want oral hearing?
YES
25. Oral Hearing
YES
26. Validation Completion and Case Meeting/ Deliberation
NO
Steps 8 and 14
27. Draft Decision
28. Deliberations on the Draft
NO
29. Consensus achieved?
YES
30. Verification including confidentiality check
31. Adoption of the Final Decision
32. Is translation needed?
YES
33. Translation
NO
34. Signing of the Final Decision
35. Service to the parties
36. Publication of Final Decision
END