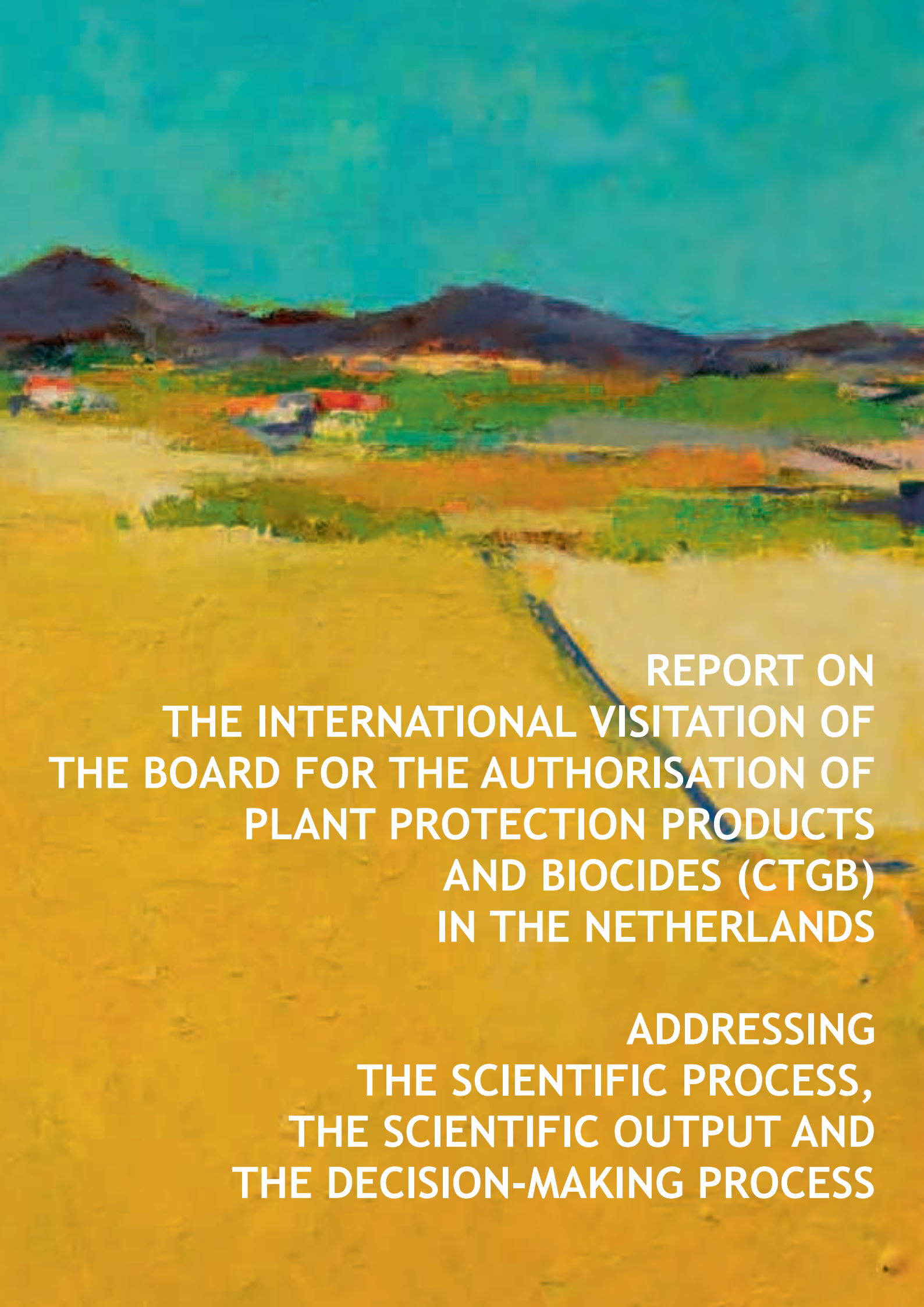

REPORT ON THE INTERNATIONAL VISITATION OF THE BOARD FOR THE AUTHORISATION OF PLANT PROTECTION PRODUCTS AND BIOCIDES (CTGB) IN THE NETHERLANDS

ADDRESSING THE SCIENTIFIC PROCESS, THE SCIENTIFIC OUTPUT AND THE DECISION-MAKING PROCESS

Cover: Painting: Jan Groenhard “L’ete en Provence” (detail) oil on linnen 40x40 cm. Layout: Marlou Heinen	**Voorblad**: Afbeelding: Jan Groenhard “L’ete en Provence” (detail) olie op linnen 40x40 cm. Vormgeving: Marlou Heinen

Report on the international visitation

of the

Netherlands Board for the Authorisation of Plant Protection Products and Biocides (CTGB)

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5th July 2013

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'Be just before you are generous'

James Joyce, Ulysses

Executive Summary

On request made by Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) an international evaluation of the scientific processes used by the Ctgb and of the scientific quality of the Decisions and other technical output of the Ctgb was undertaken during the first half of 2013.

The approach taken by the International Visitation Committee (IVC) was endorsed by the Board and included a list of quality indicators for each of three focus areas (31 indicators in total). The IVC relied exclusively upon documentation and information provided by the Ctgb and relevant documentation available on websites of the European Commission and its Agencies and that of relevant international organisations. The IVC examined the academic qualifications and the extent of relevant experience of the staff of the Ctgb, as well as the systems used to manage performance, the training and development systems deployed, the peer review arrangements in place and the arrangements for responding to complaints.

Findings and observations made by IVC in completing its work addressed the role and structure of the Ctgb, its mandate and procedural transparency, compliance with relevant legislation and guidance documentation, recruitment and staffing policy, procedures for management of performance, the peer review systems used, the arrangements for documentation of risk assessments and of Decisions made as well as mechanisms for the early identification of relevant developments in science and technology.

Twenty nine recommendations developed by the IVC were commended to the Board of the Ctgb for its consideration, one of which was an over-arching recommendation, four related to the mandate of the Ctgb, one to compliance with relevant legislation and guidance documentation, thirteen to recruitment and staffing policy, three to management of performance, four to peer review processes and systems, and three to the documentation of risk assessments, peer reviews and Decisions.

The IVC found no instances in which either a Ctgb risk assessment opinion or a risk management Decision reviewed was considered to be inadequately grounded or to be inappropriate. The IVC is convinced that a higher level of openness and transparency by the Ctgb would minimise the possibility of third parties having a different perception. The overall conclusion reached was that the Ctgb is a science-driven regulatory agency that is well run; staff and management of the Ctgb are enthusiastic and collegial in their approach; and the work atmosphere as experienced by the IVC was very pleasant.

Samenvatting

Op verzoek van het College voor de Toelating van Gewasbeschermingsmiddelen en Biociden (Ctgb) werd gedurende de eerste helft van 2013 door een onafhankelijke internationale visitatiecommissie een evaluatie gemaakt van de kwaliteit van de wetenschappelijke processen, de wetenschappelijke besluitvorming, de Besluiten zelf en van andere wetenschappelijke documenten en publicaties van het Ctgb.

Het plan van aanpak van de Internationale Visitatie Commissie (IVC), bekrachtigd door het College, omvat een lijst van kwaliteitsindicatoren voor elk van de drie aandachtsgebieden (31 indicatoren in totaal). De IVC heeft gebruik gemaakt van alle documentatie en informatie verstrekt door het Ctgb, van relevante informatie verkregen via de internetpagina's van de Europese Commissie en haar agentschappen en die van relevante internationale organisaties. De IVC heeft zich gericht op de academische kwalificaties en de mate van relevante ervaring van de medewerkers van het Ctgb, de systemen die worden toegepast voor het vastleggen van prestaties door medewerkers, opleiding en verdere wetenschappelijke ontwikkeling, op de toegepaste procedures voor z.g. 'peer reviews' en de procedures voor het behandelen van klachten.

Bevindingen en opmerkingen van de IVC vastgesteld bij de uitvoering van haar werkzaamheden betreffen met name de rol en structuur van het Ctgb, het mandaat van het College, de procedurele transparantie, de naleving van relevante wetten en begeleidende richtlijnen, en het personeelsbeleid, met name de werving en carrièrebegeleiding van wetenschappelijke medewerkers. Andere bevindingen van de IVC betreffen het 'peer review' systeem van wetenschappelijke evaluaties, de regelingen voor de documentatie van de risicobeoordelingen en van de Besluiten van het College alsook de mechanismen voor het vroegtijdig opsporen van relevante nieuwe ontwikkelingen in de wetenschap en technologie van risicobeoordelingen van pesticiden en biociden.

De IVC heeft negenentwintig aanbevelingen opgesteld en ter overweging aangeboden aan het Ctgb College en senior management waaronder een overkoepelende aanbeveling, vier aanbevelingen in verband met het mandaat van het Ctgb, een met betrekking tot de naleving van de relevante wetgeving, het Ctgb reglement en richtlijnen, dertien met betrekking tot werving en personeelsbeleid, drie aangaande carrièrebegeleiding en prestatiebeleid, vier betreffende het 'peer review' proces en beleid, en drie betreffende de documentatie van risicobeoordelingen, 'peer reviews' en de Besluiten van het College.

De IVC heeft geen enkel geval aangetroffen waarin een Ctgb risicobeoordeling of een risicomanagement besluit werd beschouwd als onvoldoende gefundeerd of onjuist. De IVC is ervan overtuigd dat een hogere mate van openheid en transparantie in de werkwijze en besluitvorming van het Ctgb de mogelijkheid zal minimaliseren dat derden een andere perceptie hebben van de aard en kwaliteit van het werk van het Ctgb. De algemene conclusie was dat het Ctgb een wetenschappelijk regelgevend agentschap is dat goed wordt geleid; het wetenschappelijk personeel en leidinggevenden van het Ctgb zijn enthousiast en collegiaal in hun aanpak en de werksfeer zoals ervaren door de IVC was zeer aangenaam.

1 Introduction

1.1 On request made by the Chairman of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) in November 2012 Dr Herman Koëter, Scientific Director of the European Food Safety Authority (EFSA) until November 2008, was asked to organise an international evaluation of the scientific processes used by the Ctgb and of the scientific quality of the Decisions and other technical output of the Ctgb. During the course of an orientation meeting on 6th December 2012, the assignment was accepted, subject to the approval of the Board on 18th December 2012 and to the availability of appropriate experts to serve on the international evaluation committee to be established.

1.2 During a second meeting on the 9th January 2013, with the Chairman and Director of the Ctgb it was agreed that the International Visitation Committee (IVC) should have five members. The Terms of Reference for the work of the IVC were also agreed during that meeting (*cf* Appendix 1). The Terms of Reference required that the IVC address in particular: -

a) the scientific quality and legal compliance of Decisions made regarding the authorisation of plant protection and biocidal products, and
b) the validity of such Decisions over time, taking into consideration developments in updating EU legislation and progress achieved in science and technology.

1.3 The members of the International Visitation Committee (IVC) were identified and selected on the basis of considerations aimed at ensuring the presence in the Committee of: -

a) independent senior scientists with high-level public sector experience in the EU,
b) expertise in pesticide active substance and product evaluation and approval for each of the three EU zones,
c) balanced in relation to expertise in both plant protection and biocide risk assessment as well as in relation to the range of scientific disciplines involved.

In addition, one senior expert with broad experience and expertise in EU legal matters was recommended as advisor to the IVC. By letter of 21st January this proposal was presented to the Ctgb Board. On 28th January 2013, the proposed membership of the IVC was confirmed by the Board of the Ctgb

1.4 The members of the IVC who were formally appointed by the Board and whose CVs are provided in Appendix 2, were: -

- Dr Sari Autio, Finland.
- Dr Ursula Banasiak, Germany
- Dr Herman Koëter, Belgium (Chairman).
- Dr Mark R Lynch, Ireland.
- Prof Vittorio Silano, Italy.

In addition to the members, the legal advisor to the Committee was: -

- Mr Antoine Cuvillier, Belgium.

1.5 Prior to commencing their work, the members of the IVC and the legal advisor signed Declarations of Interest with regard to their assignment as members of the IVC and Declarations of Confidentiality with respect to access provided to confidential information in dossiers to be reviewed. The signed declarations of interest and of confidentiality are provided in Appendix 3.

2 Approach taken by the IVC

2.1 The Activity Plan

2.1.1 An Activity Plan (referred to as work-plan in the terms of reference) was submitted for comment to the Board and Senior Management of the Ctgb on 26th February. The Activity Plan contained an outline of the approach to be taken by the IVC in evaluating the scientific process, the scientific output and the decision-making processes of the Ctgb. It included a list of quality indicators for each of the three focus areas (31 indicators in total) as well as an initial list of documents requested. The Activity Plan included reference to concern that a substantial number of documents requested are likely to be available only in the Dutch language. The final element of the Activity Plan consisted of the schedule envisaged for its work, starting with the inaugural meeting on 1st February and ending on 3rd July with the presentation of its report.

2.1.2 The text of the Activity Plan is provided in Appendix 4.

2.2 The Visits

2.2.1 In conducting its work, the members of the IVC, other than the legal adviser, visited the premises of the Ctgb in Wageningen on several separate occasions: -

- First meeting: 1st and 2nd February 2013,
- Second Meeting: 16th and 17th April 2013,
- Third Meeting: 10th through 13th June 2013,
- Fourth Meeting: 26th June 2013.

However, one member participated in the first meeting by video connection and in the fourth meeting by telephone link. The report of the IVC was presented to the Chairman and to the Director of the Ctgb on the 5th July by Dr Herman Koëter (at the request of the Chairman of the IVC moved from the 3rd July).

2.2.2 During the visits, meetings were held with the Chairman and members of the Board of the Ctgb, the Director and management of the Ctgb, with team leaders and co-ordinators as well as with a considerable number of scientific assessors and project managers.

2.2.3 In addition to their visits to Wageningen, the members of the IVC discussed various elements of their work *via* emails throughout the period allocated for its work and *via* teleconferences convened on 20th February 2013, 14th March 2013, 2nd April 2013, 13th May 2013, 27th May 2013 and 24th June 2013.

2.3 Documentation and Information Used

2.3.1 The scientific quality of data evaluations prepared, and consequently of decision-making based upon those evaluations, while dependent in the first instance on the quality and extent of the data submitted to support applications made, depends ultimately on the quality of the work delivered by the scientific assessors deployed and on the quality of the work of their supervisors, management and Board. The IVC in conducting its work focussed particular attention on the level of education, training, including continuous on-the-job training and the extent of relevant experience of Ctgb staff, and the organisational arrangements deployed, but also conducted a review of: -

- a selection of evaluations prepared for and authorisation Decisions made by the Board;
- a Draft Assessment Report (DAR) for a plant protection active substance prepared by the Ctgb on behalf of the European Commission; and
- a Competent Authority Report (CAR) for a biocidal active substance prepared on behalf of the European Commission.

2.3.2 The IVC for the purposes of its work relied exclusively upon the documentation and information provided by the Ctgb and relevant documentation available on websites of the European Commission and its Agencies and as well as that of relevant international organisations such as the Organisation for Economic Co-operation and Development (OECD). During its visitation from 10th to 12th June, the Ctgb provided full access to all staff of the organisation and to the files and documentation systems maintained by it, in order to facilitate the IVC's understanding of the management and organisation arrangements of the Ctgb as well as of its working procedures. The documentation and access provided included unrestricted access to risk assessments prepared on the basis of which Decisions of the Board were made, as well as access to: -

- the Ctgb database, and website,
- the guidance documentation used by Ctgb scientific assessors,
- documentation generated during the scientific assessment of applications submitted to the Ctgb for the approval of active substances and for the authorisation of products for the Dutch market,
- the minutes of meetings of the Board of the Ctgb,
- the records maintained in monitoring the performance of staff (viewing of personnel files selected by the IVC),
- individual staff members whether working on scientific assessment, co-ordination, project management, information management or other duties as well as to senior management and Board members.

The IVC acknowledges that additional pertinent and useful information was gained by its members though conversations with Ctgb staff during the course of a series of informal meetings and interviews.

2.3.3 The forms used by the IVC in analysing and evaluating: -

- the professional qualifications of scientific staff and external scientific consultants,
- scientific process quality,

- selected product dossiers,
- selected draft DARs and CARs prepared by the Ctgb, and
- the overall management and decision-making by the Board,

are provided in Appendix 5. In those forms all of the criteria listed in the Activity Plan (Appendix 4) were incorporated. A listing of documentation requested in relation to the work of the Ctgb is provided at Appendix 6, while a listing of specific written questions posed and the responses provided is provided in Appendix 7.

2.3.4 PowerPoint™ presentations made by the Chairman of the Board, the Director and senior staff members during the first and second meetings with the IVC are provided in Appendix 8. Those presentations provided very useful insights to the organisation and working procedures used by the Ctgb.

2.3.5 The IVC was pleased by the courtesy and willingness to provide documentation, information and responses to the various questions posed, on the part of the members of the Board, the Director and senior management of the organisation as well as by the many staff members it met. The efforts made to provide English translations of selected Dutch language documents requested were appreciated. The members of the IVC noted that due to limited translation capacity (both in terms of time and resources available) translations of all key documentation in the Dutch language could not be provided. Since Dutch is the mother tongue of one of the members of the IVC, that limitation was satisfactorily managed by the IVC in conducting its review.

2.4 Analytical Approach Used by the IVC

2.4.1 The observations, findings, conclusions and recommendations offered in this report reflect the professional experience of the IVC members and their appreciation of the approaches considered most likely to be successful. The members of the IVC agreed that the main factors that influence the quality of evaluations generated by scientific assessors and of the consequent Decisions of all Regulatory Authorities are governed by the professional expertise and experience of the scientists deployed to conduct hazard and risk assessments and of their managers as well as by the policies adopted by those Regulatory Authorities in relation to: -

a) The academic qualifications of the persons appointed, whether staff members or external experts, to undertake assessments in the various subject areas involved (physical, chemical and technical properties; analytical methods; efficacy; toxicity (human and environmental) and exposure assessment; residues profile; fate and behaviour in the environment; impact on non-target species), as well as in relevant support and management roles.
b) The extent of relevant experience of the persons appointed, whether staff members or external experts, to undertake assessments in the various subject areas involved (physical, chemical and technical properties; analytical methods; efficacy; toxicity (human and environmental) and exposure assessment; residues profile; fate and behaviour in the environment; impact on non-target species), as well as in relevant support and management roles.

c) The successful implementation of a performance management systems for all staff, tailored to the particular needs of the organisation, such that it: -

   i. involves development of business plans for the overall organisation and its constituent elements, that are reviewed on an annual basis;

   ii. includes development of role profiles (individual tasks and responsibilities) for each staff member, with reviews of performance conducted at least on an annual basis; and

   iii. includes a mentoring system for newly appointed staff by experienced staff members.

d) In-house and external training and development programmes for all staff, targeted to ensure that scientific assessors, managers and support staff continue to develop and maintain the required levels of expertise.

e) The quality of the peer review arrangements for evaluations prepared by individual Ctgb scientific assessors, within each discipline (physical, chemical and technical properties; analytical methods; efficacy; toxicity (human and environmental) and exposure assessment; residues profile; fate and behaviour in the environment; impact on non-target species).

f) The quality of the peer review arrangements for evaluations prepared by external contractors by discipline (physical, chemical and technical properties; analytical methods; efficacy; toxicity (human and environmental) and exposure assessment; residues profile; fate and behaviour in the environment; impact on non-target species).

g) The quality of the peer review arrangements for proposed Decisions to ensure their quality prior to their submission for consideration by those responsible for risk management and decision-making.

h) The quality of the responses to complaints or formal objections made concerning Decisions by applicants for the authorisation of particular products.

i) The quality and level of professional preparedness and adaptability with regard to scientific developments in risk assessment having particular regard to new scientific evidence that may affect earlier Decisions.

2.5 Transparency

2.5.1 Although the scientific quality of evaluation work undertaken by the staff of a regulatory authority and of decision-making by the relevant risk managers based upon those evaluations may be of a high standard, the robustness of the decision-making process and of the scientific quality of the evaluations underpinning those Decisions would not necessarily be apparent to stakeholders, outside assessors or auditors, or the general public, in the absence of complete transparency in the scientific process and in decision-making. It was noted that the Ctgb publishes its Decisions, including the final risk assessment upon which individual Decisions are based. Greater transparency can be best secured by making available: -

a) detailed documentation of the risk assessments prepared including a summary of issues raised during the peer review processes undertaken (sector by sector and on

an overall basis) and of the outcome of peer reviews, to ensure the quality and consistency of evaluations prepared, and

b) detailed documentation of the deliberations of the risk managers on individual applications as well as of the rationale for modifications adopted in relation to particular Decisions proposed.

3 Observations and Findings

3.1 The Role and Structure of the Ctgb

3.1.1 The Ctgb is a regulatory agency established by the Dutch Government in 1993 resulting from a restructuring of the College voor de Toelating van Bestrijdingsmiddelen (CTB). It became an autonomous administrative body on 1st January 2000. Decisions of the Ctgb are required to reflect the policies of currently four ministries, Economic Affairs (EZ) which is *inter alia* responsible for agriculture, Infrastructure and Environment (I&M), Health, Welfare and Sports (VWS), and Social Affairs and Employment (SZW). The Ctgb is accountable to those Ministries for which it prepares a work programme and a budget and publishes an annual statement of accounts, quarterly reports, and an annual report. The Supervisory Board, established by the controlling ministries, is the final arbitrator determining whether or not the Ctgb conducts its business as required.

3.1.2 The Ctgb has responsibility for both risk assessment and risk management in the regulation of plant protection products and biocides in the Netherlands. The Ctgb is responsible for the authorisation, or rejection, of plant protection and biocidal products for the Dutch market on the basis of assessments of the risks arising for human and animal health and for the environment, taking account of relevant national and EU legislation. The Ctgb is also responsible for the preparation of Draft Assessment Reports (DARs) for plant protection active substances and Competent Authority Reports (CARs) for biocidal active substances where the Netherlands has been appointed Rapporteur Member State for particular active substances, and furthermore is required to prepare comments on DARs and CARs prepared by other Member States on behalf of the Netherlands. In addition, the Ctgb is required to provide advice and support to the Ministries to which it is accountable on both national and European issues in relation to plant protection and biocidal products and their effects.

3.1.3 The members of the IVC were impressed by the extent of the staff resources provided to the Ctgb. Those resources reflect the recognition by the Dutch Government of the importance of the Ctgb's regulatory work. The increase in the staffing level of the Ctgb reflects the increased demand placed upon it: -

- to process applications for the authorisation of plant protection and biocidal products intended for the national market in a timely manner;
- to address the increase in workload occasioned by its responsibilities regarding the preparation of DARs for plant protection active substances and CARs for biocide active substances; and

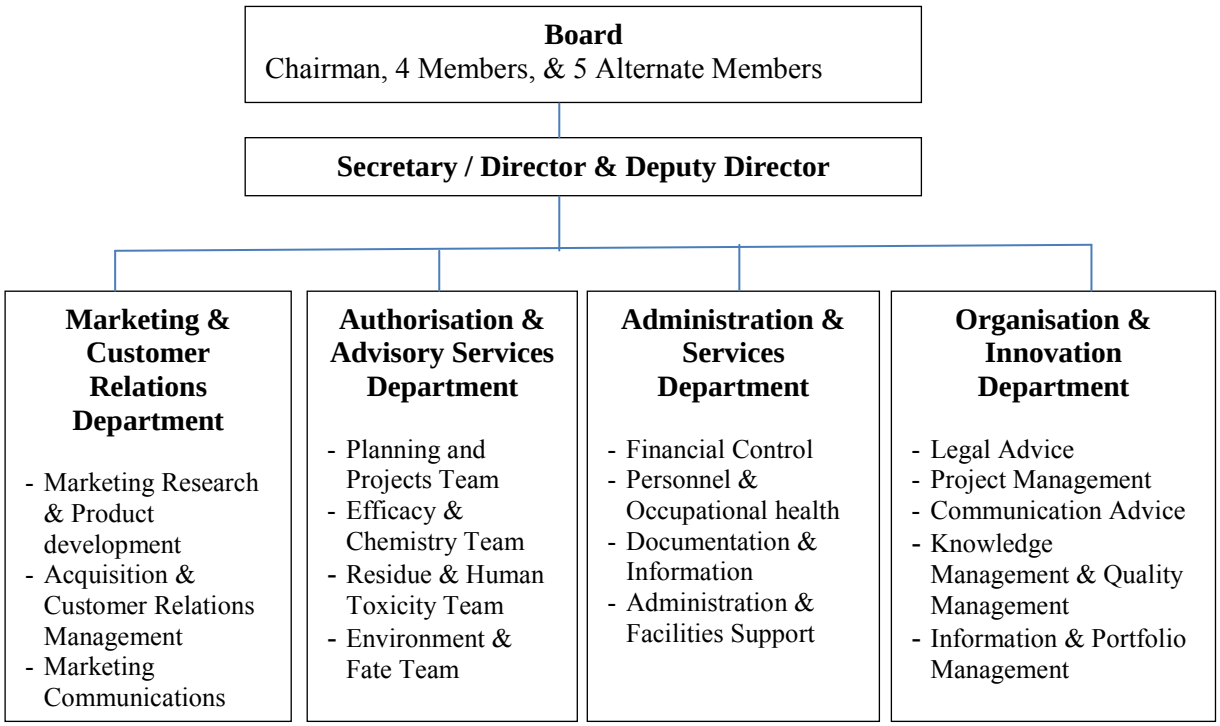
- to review and comment on DARs and CARs prepared by the competent authorities of other Member States.

The increase in staff resources and workload over the period since 2000 is reflected in the following table: -

Year	Staff number (FTE)	No of applications processed	No of DARs and CARs prepared	No of DARs and CARs on which comments were prepared
2000	53	34	*	*
2005	60	110	*	*
2008	60	90	1	83
2009	66	116	5	58
2010	70	121	2	48
2011	77	139	10	72
2012	89	234	3	114
2013 (May)	117	*	2	40

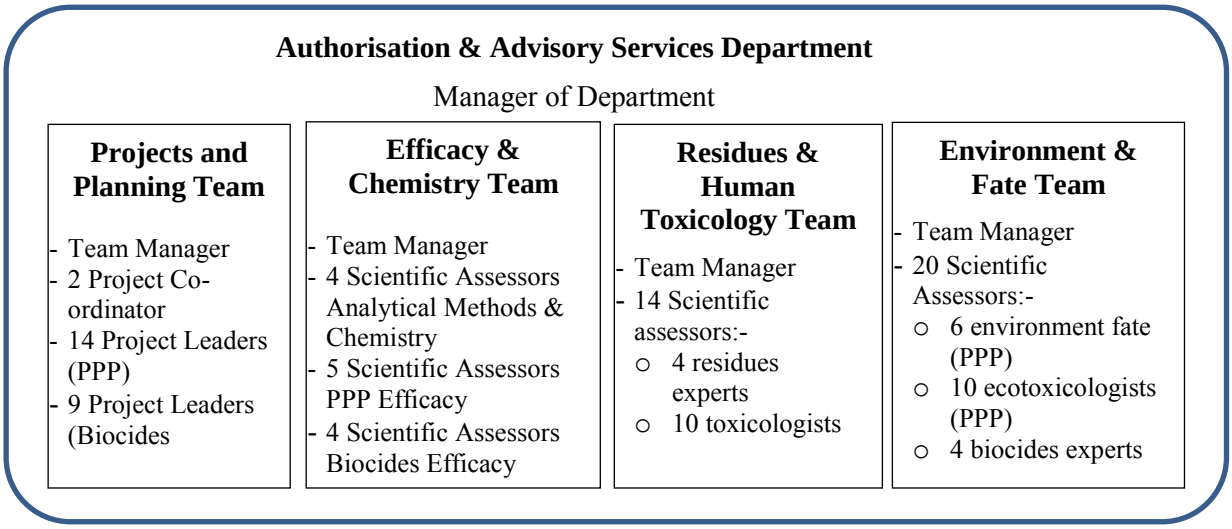
* data not available

3.1.4 The Ctgb currently has a total workforce of some 126 persons (117 FTE's) and a Board of 5 members including the Chairman, and 4 alternate members. In practise meetings of the Board are attended by both its members and alternate members (including one vacancy). The deliberations and Decisions of the Board are recorded in the minutes of its monthly meetings. The staff of the Ctgb, consisting of scientific assessors, project leaders and co-ordinators, support staff, ancillary staff and management are organised as follows: -



3.1.5 The Authorisation and Advisory Services Department is responsible for drafting the science based risk assessments and draft Decisions for submission to the Board. The Board in turn reviews those risk assessments and draft Decisions and makes its final Decisions following, where appropriate, amendment of the proposed risk assessments and of the proposed Decisions.

3.1.6 The Authorisation and Advisory Services Department is structured into four teams as follows: -



3.2 Mandate of the Ctgb and Procedural Transparency

3.2.1 In recent years it has become the norm at EU level, to separate scientific risk assessment and risk management functions of regulatory bodies such that risk management is the responsibility of a separate body or organisation or at least the subject of separate and distinct processes. While this approach has been adopted by some Member States, it may not be feasible in others because of the consequential need to duplicate certain competencies and areas of expertise within the bodies responsible for risk assessment and for risk management.

3.2.2 In accordance with the Decree providing the Ctgb with its mandate[1] responsibility for both risk management and risk assessment is clearly vested in the Board of the Ctgb while the Director and his staff are specifically mandated to prepare the required scientific risk assessments and proposed risk-management Decisions. This institutional arrangement is understood by the IVC to be designed to distinguish the individuals responsible for the final risk assessments and Decisions made (by the Board) from those responsible for preparing the proposed risk assessments and draft Decisions. The IVC recognised that this arrangement is especially important and therefore should be fully reflected in the mandate of the Ctgb, in its structure and organisation, in documented working methods and processes and in the Ctgb's operating culture. A more convincing and clear-cut demarcation of roles would be desirable in the light of the overarching objective to enhance transparency.

[1] The Decree on the Mandate, Authorization and Representation by the Ctgb 2011, 3 March 2011, Government Gazette No 4789, 18 March 2011

3.2.3 In the interests of ensuring that the lines between the two roles do not become blurred and therefore that the personal and professional responsibilities on which Decisions are made are not rendered unclear, it is in necessary that the deliberations of the Board be fully documented and in particular that the rationale for modifications adopted by the Board in relation to particular Decisions proposed, be fully documented.

3.2.4 While Regulation (EC) No 1049/2001[2] guarantees public access to European Parliament, Council and Commission Documents, it does not *per se* apply to Member State institutions. Nevertheless the inclusion of more detailed information on the basis for Decisions made in the documentation published on the Ctgb website would be consistent with the principles that led to the adoption of that Regulation. Additional guidance on handling commercially sensitive information is provided in relevant specific legislation: -

a) Regulation 1107/2009[3] sets out the approach to be followed in the case of plant protection products (*cf* the 41st Whereas Clause) and defines the type of information that should in principle not be subject to disclosure (*cf* Article 63), and
b) Regulation 528/2012[4] specifies the scope of the information that should and should not be released (*cf* Article 66) in the case of biocidal products.

3.3 Compliance with Relevant Legislation and Guidance

3.3.1 The members of the IVC on reviewing the evaluation and decision-making of the Ctgb for a selection of Decisions made, found that the Ctgb in conducting its work complies with the requirements of relevant EU and National Legislation and decrees as listed in Appendix 9.

3.3.2 The IVC noted that authorised English translations are available for the "Decree on the Mandate, Authorisation and Representation by the Ctgb, 2011" and "Regulations for the Working Methods of the Board for the Authorisation of Plant Protection Products and Biocides Decree". On reviewing these documents the IVC noted the following: -

a) In the Decree the functions of Project Leader A, Project Leader B, and Management Assistant T and A are not defined;
b) In the Regulations the words "Decision" (which is an act) and "decision-making' (which is a process) are used interchangeably although they have different meanings;
c) There is reference to the function of "deputy member" (article 8 and 11.5) but this function is not defined. Perhaps "alternate member" (plaatsvervangend lid) is meant;

[2] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission Documents. OJ No 145, 31.5.2001, p43

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/414/EEC. OJ No L309 24.11.2009 p1

[4] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ No L167, 27.6.2012, p1

d) The meaning of article 9.2 is not clear. The IVC interpreted this article as stating that the minutes of the Board are publicly available but redacted of confidential data;

e) Article 14 states that the Board will appoint a Chairman from among its members: however, on the basis of discussions with the Board it emerged that the Chair was appointed by the Minister for Economic Affairs;

f) Article 17.1 states that the secretary is responsible for the finalisation of the Board's Decision: probably the word finalisation should be understood to mean "recording and implementing";

g) Article 25 states that the Chairman is authorised to take Decisions on behalf of the Board on a series of issues. However, decision-taking authority can also be delegated to the Secretary (*cf* Article 26). Furthermore, Article 27 provides for further delegation of decision-making. The scope of Decisions that can be made by the Secretary or by individual members of the Board is unclear and can lead to a loss of clear distinction between risk assessment and risk management procedures. The original Dutch language version of Article 27 is much clearer;

h) Article 29 refers to 'normal operation' but this term is not defined;

i) Article 30 refers to 'legal representation of the Ctgb' and mentions both the Secretary and the Chair of the Board. It is unclear therefore who is the legal representative of the Ctgb.

3.3.3 Although the members of the IVC did not have the opportunity to review all the Guidance Documents used by the Ctgb, it was concluded, on the basis of *ad hoc* spot checks, and on the basis of a detailed review of a selection of dossiers (*i.e.* 5 authorisation files, a DAR and a CAR), that the key guidance made available for the purpose of evaluation and decision-making for both plant protection and biocidal products is adequately reflected in the Ctgb Manuals and Handbooks for staff. The listing of Guidance documentation used by the IVC is provided in Appendix 10.

3.3.4 The members of the IVC appreciated the extent of the participation of Ctgb staff members in the development of EU Guidance Documentation.

3.3.5 The reviews undertaken by the members of the IVC of a number of dossiers compiled in the recent past by the Ctgb that were selected at random for: -

- 3 plant protection and 2 biocidal product authorisations,
- a DAR for a plant protection active substance prepared by the Ctgb for the European Commission and the European Food Safety Authority (EFSA), and
- a CAR for a biocidal active substance prepared by the Ctgb for the European Commission and the European Chemicals Bureau (ECB),

served as the basis for the observations and findings set out in the following paragraph.

3.3.6 The findings and observations that follow were compiled in relation to the criteria developed prior to commencing the reviews and are summarised hereunder: -

a) Criterion: *Confirmation of compliance of the Decision, DAR or CAR with adopted guidance and/or legislation*: -

i. Evaluation documentation prepared by the Ctgb was judged to be in compliance with adopted legislation, guidance and technical notes;

ii. Evidence of compliance with the requirements specified in the legal instruments approving active substances was not documented.

b) Criterion: *Clarity and comprehensibility of the Decision or scientific opinion especially in terms of data available, data utilised*

i. Evaluation documentation prepared by the Ctgb provided, for the most part, the required clarity as well as evidence of being comprehensive;

ii. Evaluation documentation prepared did not always specify with sufficient clarity where evaluations and conclusions from relevant DAR, CAR or EFSA Conclusion Documents were reproduced and relied upon;

iii. In the case of mutual recognitions, the evaluation documentation did not always specify with sufficient clarity where reliance on evaluations and conclusions from other Member States were relied upon and where Dutch specific data and/or evaluation were required;

iv. In some cases residues data were reported in summary form and consumer risk assessments did not include calculation sheets thereby leading to a lack of transparency;

v. In the case of the CAR reviewed, it was not clear whether the additional data to be provided were considered essential for completion of the evaluation of the active substance or were merely considered confirmatory in nature.

c) Criterion: *Weight of evidence considerations, variability and uncertainties and assumptions, conclusions and recommendations*

i. Use of a weight of evidence approach was evident in the evaluations conducted although variability and uncertainty issues were not always clearly documented;

ii. It was noted that reference to potential for endocrine disruption was not specifically mentioned in the evaluation of applications for products containing active substances suspected to have such potential;

iii. It was noted that reference to potential for development of resistance of target organisms was not specifically mentioned in the evaluation of applications for products containing active substances known to have such potential;

iv. While it is recognised that confidential business information must be protected, in at least one case a statement was not included to indicate that the evaluation conducted took account of relevant impurities and by-products present;

v. In the case of the DAR reviewed comments listed in the reporting table regarding a range of issues, led to the members of the IVC

observing that perhaps a more robust peer review within the Ctgb was required before the DAR was finalised.

d) Criterion: *Evidence of collegial feedback and/or peer reviews of drafts*

   i. The record of the evaluations (risk assessment and risk management) reviewed did not include documentation of the internal peer review process and dialogue nor did it include documentation of dialogue within the Board or between the Board and the Secretariat;

   ii. In the case of the DAR and the CAR reviewed, the external peer review was well documented in accordance with the respective EFSA and ECB procedures;

e) Criterion: *Level of consistency and coherence of the DAR or CAR with other DARs/CARs*

   i. The DAR and CAR prepared by the Ctgb reviewed by the members of the IVC were found in general to be consistent and coherent with those prepared by other Member States.

f) Criterion: *Evidence of recognition and acceptance of the DAR or CAR by EFSA, ECB, EU member states*

   i. The working documents provided served to confirm the quality of the draft DAR and CAR prepared by the Ctgb that the IVC reviewed but would have benefited from a more structured internal peer review process;

g) Criterion: *Level of adequateness of the response to comments, questions and suggestions from Member States' experts*

   i. Evidence of satisfactory response by the Ctgb as RMS is provided by the DAR Addendum prepared by the Ctgb as well as by the response to comments contained in the reporting and evaluation tables;

   ii. The Ctgb was open to accept comments and was prepared to seek a compromise as evidenced by the extensive debate at European level on a wide range of issues.

3.3.7 The IVC noted that in recent past, the Board of the Ctgb undertook the systematic review of DARs and CARs prepared by the Secretariat prior to their being submitted to the European Commission, EFSA and the ECB. That approach is endorsed by the IVC as good practice and should be continued.

3.4 Recruitment and Staffing Policy (Internal and External)

3.4.1 The number and professional qualification of staff of the Ctgb has been variable over time. A considerable increase in staff numbers has occurred recently. Depending on the extent of the workload, the Ctgb has contracted external scientists to prepare some DARs, and CARs and to perform specific higher tier risk assessments. The external consultants used are employees of recognised public organisations in the Netherlands. While such arrangements are helpful in dealing with sudden quantitative and qualitative

variations in workload, it requires substantial in-house effort to maintain quality and consistency.

3.4.2 The members of the IVC noted and were somewhat surprised at the ratio of the number of co-ordinating, project leader and team managers, to the number of scientific assessors in the Department of Authorisation and Advisory Services which was 27 to 47. The members of the IVC were also somewhat surprised to learn that a number of staff had no particular scientific qualifications, but nevertheless played a critical role in the overall work of the Ctgb.

3.4.3 Having reviewed the CVs provided by the staff involved in scientific risk assessment as well as those of project leaders, co-ordinators, management and Board Members, the IVC noted the following: -

a) CVs in general contain insufficient detail, especially with regard to experience and expertise acquired prior to joining the Ctgb;
b) A substantial number of scientific staff have been recruited within the last two years;
c) At the time of the visitation, some four project leaders and two scientific assessors did not wish to share their CVs with the IVC;
d) The number of on-the-job training events listed was not equally distributed among the staff. For most scientific staff the number of training events was rather low while the average number of days spent on external training/education was less than 3 days/year in 2012;
e) The CVs of just seven scientific staff members include a reference to the staff member being a European Recognised Toxicologist (ERT);
f) The average number of scientific publications by scientific staff, both before and following employment by the Ctgb, as reported in the CVs provided, was less than seven.

A summary of the observations noted by the IVC is provided in Appendix 11.

3.4.4 While impressed by the high level of morale displayed by the staff met and by their commitment to the work of the Ctgb, the members of the IVC were surprised that a rather flat hierarchical or grading structure was in place, a structure that the IVC believed does not adequately provide for career opportunities within the science based environment of the Ctgb, particularly for excellent performers.

3.4.5 While considerable resources are currently devoted to mentoring and in-service training of both staff and management, the members of the IVC believe that the policies in place may be rather *ad hoc* and tailored to individual preferences instead of being focussed on the broadening and deepening of scientific staff expertise.

3.4.6 It was noted by the IVC that while some scientific assessors and other staff have excellent publication records, many do not. Although confidentiality issues constrain to some extent potential for publication, such constraints should not preclude publication of papers relating to methodology for assessment of risk and the validation of such methods. Furthermore, the Ctgb database that includes risk assessments for a wide range of

products and active substances and related scientific data provides an excellent source for scientific and statistical analyses without the need to disclose propriety information. The discipline involved in the preparation of papers for publication would serve to further enhance the analytical and report writing skills of the scientists concerned while a greater emphasis on publishing papers in the scientific literature would enhance the reputation of the organisation for which they work.

3.5 Management of Performance

3.5.1 The structure and organisation of the Ctgb has been carefully considered and updated to reflect increasing work-loads while ensuring productivity and maintaining the quality of outcomes in terms of both scientific evaluation and decision-making. Clearly, the performance management system developed and used by the Ctgb has made possible the achievement of valuable results. Performance management systems provide an important mechanism to manage priorities and are of great importance in promoting and ensuring excellence while respecting deadlines established. Annual or biannual staff performance evaluations ideally are linked to incentives (*e.g.* promotion, increased responsibility), in exceptional cases to financial rewards and, if necessary, to postponement of payment of the next increment on the relevant salary scale or even to demotion.

3.6 Peer Review Process and System

3.6.1 The IVC recognised that a systematic approach is in place for the peer review of evaluations prepared by the Ctgb's scientific assessors and of evaluations prepared by outside contractors on behalf of the Ctgb. The IVC members were pleased to note that the documentation system in place within the organisation requires that the completion of each such peer review be systematically recorded.

3.6.2 However, the members of the IVC were concerned that it would be difficult to conduct and oversee detailed peer reviews by sector and on a global basis, since a number of project leaders do not have sufficient scientific training to facilitate their appreciating the complexities involved. It was noted that a step does not exist in the overall procedure to make possible an opportunity for all the scientific experts that contributed to a specific evaluation to collectively review the end result of their joint efforts.

3.6.3 On reviewing selected authorisation Decisions and the supporting documentation appended to published Decisions, as well as on reviewing a DAR for a plant protection active substance and a CAR for a biocidal active substance prepared by the Ctgb for the European Commission, the IVC noted that documentation of the peer reviews (findings, disagreements, consensus-building, *etc.*) was absent. This observation was confirmed by the comments and explanations provided by members of staff, management and the Board, during the course of our various meetings.

3.7 Documentation of Risk Assessments and of Decisions

3.7.1 The format used in preparing scientific risk assessments for consideration by the Board of the Ctgb and the format in which Decisions are presented, have evolved through experience gained over the years. The documentation published by the Ctgb for authorisations granted, provides a clear and explicit explanation of the basis for and the overall conclusions reached regarding each such authorisation. However, on the basis of the review of selected authorisation files, the members of the IVC considered that the inclusion of additional information in the documentation generated was desirable, in particular: -

a) material summarising the issues and the conclusions reached during the peer review process; and
b) a summary of issues raised by the Board and the conclusions reached during the consideration of the Board of each risk assessment, as well as the conclusions reached to manage the risks identified.

3.7.2 Considerable improvements have taken place in the structure of the format recommended for registration reports at European level, formats that could be used by the Ctgb to its advantage, thereby facilitating cooperation with the regulatory authorities of other Member States while at the same time improving the transparency of its own risk assessment and risk management processes.

3.8 Mechanism for Early Identification of Developments in Science and Technology Relevant for the Work of the Ctgb

3.8.1 The Ctgb currently has systems in place to monitor the availability of new scientific data, information and techniques relevant to its work and to be regularly informed of the availability and outcome of monitoring programmes that may be of importance for and trigger the review of authorisations already issued.

3.8.2 While the resources devoted to such work by Ctgb are recognised, the members of the IVC noted that only one individual, though apparently excellent in searching and finding information, may not be scientifically well-equipped to execute this important task. The limited time resources allocated to scientific staff for this purposes does not allow them to keep up-to-date with relevant scientific developments.

4 Recommendations

4.1 Introductory Remarks

4.1.1 The IVC in the framework of an overall positive appreciation of the Ctgb and its work, gained though evaluation of the its structure, staff, working methodologies and Decisions, would like to suggest and respectfully recommend both careful consideration and implementation by its management and Board, of the recommendations set out in the following paragraphs. It is acknowledged that some of the recommendations address

transparency issues rather than issues relating to the quality of Ctgb scientific practice and procedures.

4.1.2 The members of the IVC are aware that taken globally, implementation of the recommendations made may require additional resources, and therefore, depending on the availability of resources, may have to be implemented using a step-wise approach.

4.2 Mandate and Transparency

4.2.1 It is important that the lines between risk assessment and risk management do not become blurred. Therefore, to ensure that the basis on which particular Decisions are founded remains clear and distinct, it is necessary that the rationale for modifications adopted in relation to particular risk assessments and Decisions proposed be fully documented. It is therefore recommended that the documentation published for all future authorisations granted (or refused) include a summary of the rationale for modifications of proposed Decisions that are adopted by the Board. While Regulation (EC) No 1049/2001 [2] which guarantees public access to European Parliament, Council and Commission Documents, does not apply to Member State institutions, the approach recommended on the inclusion of more detailed information on the basis for Decisions made in the documentation published on the Ctgb website, is consistent with the principles that led to the adoption of that Regulation.

4.2.2 In the interest of transparency the IVC also recommends that Board Decisions, those elements of Board meeting minutes that concern authorisations and the parts of minutes of scientific staff meetings that deal with risk assessment be also drafted in English that being the most commonly used language in the EU for scientific purposes.

4.2.3 Furthermore, the IVC recommends that authorisation documentation published by the Board include details of any modification made by the Board of proposed Decisions, together with the rationale for such modification. Implementation of this recommendation is deemed essential by the IVC to ensure that the lines between the risk assessment and risk management roles do not become blurred such that the basis on which Decisions are made are rendered unclear.

4.2.4 Finally, the IVC would like to stress that for the future, Decisions of the Board regarding authorisation of products include a paragraph stating that the evaluation prepared and Decision made are in compliance with **[**insert reference to the relevant national and/or EU legislative documents] and reflect application of relevant guidance documentation [insert the list or a reference to a published list of the applicable national, EU and OECD guidance documents].

4.3 Compliance with Relevant Legislation and Guidance

4.3.1 On the basis of observations set out at point 3.3, the IVC respectfully suggests and recommends that the "Decree on the Mandate, Authorisation and representation by the Ctgb, 2011" and "Regulations for the Working Methods of the Board for the Authorisation of Plant Protection Products and Biocides Decree" be revisited and amended such that the

functions of the Board, its Chairman and the secretary/director be described with precision, thereby avoiding any uncertainty or ambiguity with regard to their responsibilities and mandates.

4.4 Recruitment and Staffing Policy (Internal and External)

4.4.1 Based upon the findings outlined at point 3.4, the IVC suggests and recommends that whenever possible for the future the recruitment of scientific assessors and their managers be confined to persons that have at least a Master's degree, or equivalent, in a relevant discipline, with a PhD qualification being preferred.

4.4.2 The IVC also recommends that efforts be made to ensure that at least all Scientific Assessors, Team Managers and Project Leaders[5] apply for and achieve European Registered Toxicologist (ERT) or an equivalent status.

4.4.3 The IVC suggests and recommends that, for transparency reasons, the CVs of all scientific staff, senior management and the Board be made publicly available on the Ctgb website, preferably in the harmonised EU format. The IVC furthermore suggests and recommends that the CVs of all scientific staff, and senior management of organisations contracted to undertake evaluative work on behalf of the Ctbg be made publicly available on either the Ctgb website or that of the contracting organisation, preferably in the harmonised EU format.

4.4.4 The IVC recognised with appreciation the mentoring system in place and recommends that this mentoring system remain in place and be further strengthened such that all newly recruited staff members, whether scientific assessors, support staff or management be mentored and coached by a senior staff member for a suitable period of at least one year following recruitment.

4.4.5 The IVC recommends that for the future, it would be preferable to restrict the involvement of external consultants to highly specialised and innovative areas of expertise not available within the Ctgb, and to acquire sufficient expertise to process all routine applications, DARs and CARs in-house. In that context and recognising the number of project leaders co-ordinators and managerial staff, in the Department of Authorisation and Advisory Services, it is respectfully suggested and recommended that future recruitment policy be geared towards a strengthening of the scientific assessment capacity of the Department with a view to: -

- alleviating work pressure on individual assessors, and
- providing more time to -
    - conduct a continuing and systematic programme of peer reviews,
    - invest in continuous professional in-service training and education, and
    - prepare papers for publication in the scientific literature (*cf* point 3.4.6).

[5] The IVC was aware that Project Leaders are in the process of acquiring International Project Management Association D status (by 2014).

4.4.6 In the interest of facilitating the retention of senior staff, particularly senior scientific staff that have developed a high degree of expertise, it is suggested and recommended that a promotion grade be introduced, such that a balanced ratio is established between the number of personnel in the standard and in the promotion grades. Promotion should be based upon interview, performance and assessment by line supervisors.

4.4.7 It is suggested and recommended that the in-service education and training policies of the organisation be reviewed and that priority be given to the improvement of the skills of scientific assessors that currently do not have Masters or PhD qualifications.

4.4.8 It is further recommended that the time allocated to scientific assessors for review of scientific literature in their fields and to attend relevant scientific conferences and seminars be reviewed with a view to ensuring that the all scientific assessors have the opportunity to maintain their expertise and be conversant with relevant developments in science and technology.

4.4.9 A further priority should be to ensure that all staff within particular disciplines and their managers and supervisors are systematically trained in use of relevant guidance documentation, mathematical and estimation models relevant to that discipline and that such training be prioritised where new or updated guidance becomes available.

4.4.10 It was appreciated by the IVC that implementation by the Ctbg of its recommendations on training will require a significant increase in the amount of time allocated to that activity. The IVC nevertheless respectfully suggests and recommends that such in-service training is essential and that while in-service training is important for all staff, the in-service training of scientific assessors and team leaders should be prioritised.

4.4.11 The members of the IVC believe that it would be a significant step forward were the scientific staff of the Ctgb to participate more actively in European and worldwide endeavours aimed at improving testing and evaluation methodologies, thereby enhancing procedures for assessment of the risks associated with exposure to plant protection products and biocides. It is therefore respectfully suggested and recommended that scientific assessors and other relevant staff be encouraged to prepare and submit papers relevant to their areas of work for publication in the scientific literature. Not only would this facilitate the scientists concerned in keeping abreast of new developments in their area, it would also serve to enhance the confidence of third parties in their scientific judgement. The publication record of staff should be one of the issues considered by supervisors and managers to inform decision-making with respect to the awarding of increments, eligibility for award of tenure or of a longer term contract, where appropriate, and eligibility for promotion.

4.5 Management of Performance

4.5.1 Although aware of the performance management systems in place, the IVC respectfully suggests and recommends that those arrangements be further strengthened such that the objectives of the organisation and of each of its Departments, Sections and

Units are clearly defined in business plans, in which appropriate targets and other performance indicators are identified. Business plans, should preferable be reviewed periodically (annually) with a view to tracking performance against targets set.

4.5.2 The IVC also recommends that, in addition to the existing function descriptions, role profiles for each individual staff member be prepared, specifying the purpose of the job, the long-term objectives identified, key competencies required, key deliverables and key performance indicators. Career opportunities could also be noted in such profiles. Individual objectives should be aligned to overall corporate objectives and vision in deriving key performance indicators. Reviews of performance of individual staff members should be conducted at least annually but ideally twice yearly, the findings of reviews completed to inform decision-making with respect to the awarding of increments, eligibility for award of tenure or of a longer term contract, where appropriate, and eligibility for promotion.

4.5.3 The IVC further suggests and recommends that performance reports be prepared for senior management by each team leader, and head of Department, Section or Unit. Those reports should be compiled on an annual or twice yearly basis and should indicate the performance level achieved for each key target identified in the business plan. Reports should include comments, observations, suggestions or recommendations where appropriate and include proposed corrective action where targets are not being achieved.

4.6 Peer Review Processes and Systems

4.6.1 The IVC respectfully suggests and recommends that evaluations prepared by each individual scientific assessor be subject to systematic peer review by one or more colleagues within the discipline concerned (physical, chemical and technical properties; analytical methods; efficacy; toxicology and exposure assessment; residues profile; fate and behaviour in the environment; impact on non-target species). Peer review meetings might be organised within each discipline to take place on a regular basis, taking account of the number of assessments to be peer reviewed. Such peer review sessions should be moderated by the manager or team leader for the discipline concerned. Ideally, evaluations for individual authorisation applications or active substance reviews should be introduced by the scientific assessor that prepared the evaluation. The lead peer reviewer should then be invited to comment on the evaluation. The introduction of a systematic approach involving all scientific assessors within each discipline will require commitment of time but would provide a valuable mechanism for ensuring the quality of evaluations prepared and of improving the skills of less experienced scientific assessors.

4.6.2 It is recommended that corresponding peer review arrangements be put in place for the peer review by Ctbg scientific assessors of evaluations prepared by outside contractors.

4.6.3 The IVC further recommends that the overall evaluations that ultimately become Appendix II to authorisation Decisions made by the Board also be subject to systematic peer review by the project leader, team leaders and scientific assessors involved from

each discipline concerned. The peer review meetings required should be organised to facilitate the availability of evaluations for consideration by the Board.

4.6.4 Finally, the IVC recommends the participation of the Ctgb in on-going arrangements for the global review of active substances using work-sharing arrangements (*e.g.* under the aegis of the OECD). This would provide a valuable additional opportunity for external peer review of evaluations prepared while at the same time would enhance the efficiency and scientific quality of reviews conducted.

4.7 Documentation of Risk Assessments, Peer Reviews and Decisions

4.7.1 The IVC respectfully suggests and recommends that, in the interests of improved transparency and improving the documentation of the peer review process, the format used in evaluating all plant protection product applications whether or not based upon mutual recognition and whether or not for new or existing products, be the standardised Registration Report (RR) format currently being updated. That format was originally developed for use by countries undertaking work-sharing using mutual recognition arrangements on a voluntary basis in the context of Directive 91/414/EEC [6] and is currently being updated for the purposes of evaluations for particular zones and mutual recognition in the context of Regulation (EC) Nº 1107/2009[3].

4.7.2 It is recommended that the conclusions reached by the Board together with the rationale for those conclusions should be inserted in RRs following removal of confidential business information, and that such documentation be published, replacing the documentation currently made available for authorisations granted.

4.7.3 It is further suggested and recommended that the Product Assessment Report (PAR) format currently being developed for use in the assessment of applications for the authorisation of biocide products be adopted and used in pace of the formats currently in use.

4.7.4 Use of the RR format in the case of plant protection product applications and the PAR format in the case of biocidal product applications, while facilitating transparency and ensuring that the peer review process is fully documented will also ensure consistency in approach regardless of whether scientific assessments are prepared in-house or by external contractors.

5 Overall Conclusions

5.1 Given the nature of the Visitation and the limited time available to conduct its work, the members of the International Visitation Committee, developed a good understanding of the organisation and functioning of the Ctgb, and in particular of its scientific processes and decision-making, but considered that the impressions gained

[6] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ No L230 19.8.1991 p1

during the visitation of this fast growing organisation provided little more than a snapshot in time and consequently were reluctant to develop and record overall and generalised conclusions. Nevertheless, the impression gained was that the Ctgb is a regulatory agency that is well run, has significant resources and has capacity above and beyond what might have been expected, based on information the IVC has at its disposal regarding capacity in other Member States.

5.2 While recognising the limitations associated with their work, the members of the IVC wish to place on record that: -

a) there were no instances in which they found either a Ctgb risk assessment opinion or a risk management Decision reviewed, to be inadequately grounded or to be inappropriate. However, a higher level of openness and transparency by the Ctgb would minimise the possibility of third parties having a different perception; and

b) the staff and management of the Ctgb were enthusiastic and collegial in their approach and the work atmosphere experienced was very pleasant.

5.3 The IVC further concluded that both the scientific quality of processes deployed and the perception of the quality achieved would be greatly enhanced on implementation of the recommendations set out in the previous section.

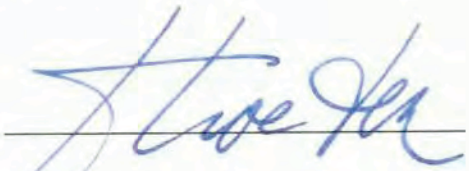
6 Acknowledgements

6.1 The IVC would like to acknowledge with thanks the co-operation, patience and assistance kindly provided by Ir. Johan de Leeuw, Chairman of the Board, the members of the Board, Dr. Ir. Luuk van Duijn, Director, Dr. Else Sneller, Deputy Director, Department and Team Managers as well as the managers and staff that we met during the course of our work.

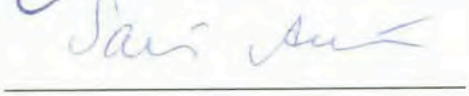
6.2 A special word of thanks is due to Dr Sjon Kortekaas, Knowledge and Quality Manager for his unstinting work in providing the Committee with documentation requested, with responses to the many questions posed by the IVC and for the provision of facilities including access to Ctgb data bases, when required. We also wish to express particular thanks to Ms Machtelt Romeyn, MSc, Knowledge and Quality Manager who in the absence of Dr Kortekaas provided a high degree of helpfulness and co-operation.

7 Signatures of the Members of the Visitation Committee

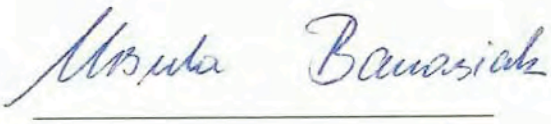
Dr Herman Koëter, Belgium (Chairman)



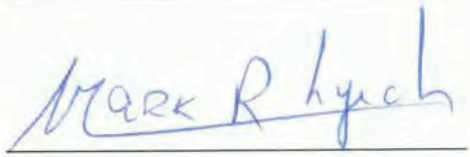
Dr Sari Autio, Finland



Dr Ursula Banasiak, Germany



Dr Mark Lynch, Ireland



Prof Vittorio Silano, Italy

Mr Antoine Cuvillier, Belgium (Legal Advisor)

Appendix 1

Terms of Reference of the IVC

ctgb

Terms of Reference - Visitation Ctgb 2013

Objective and scope of the international visitation
The objective of the international visitation is to assess the independence, the scientific quality and the legal compliance with EU and national regulations of the formal decision making process and decisions content following requests for the authorisation of plant protection products and biocides in the Netherlands. The aim of this objective is to receive a reliable, independent and internationally oriented assessment of the current quality of formal decisions being based on current state-of-the-art science and in compliance with legal requirements, or, suggestions and advice on possible improvements of aspects of the scientific decision making process and/or decision content which are considered essential for ensuring independent and high quality outputs of the Ctgb.

The International Visitation Committee (IVC) is requested to address the following areas:
- The scientific quality and legal compliance of the decisions on authorisation of pesticides and biocides. In particular:
  - Quality: the overall scientific and technical quality of the risk assessments that are prepared by the secretariat to substantiate the formal decisions by the board,
  - Process: the (internal) evaluations of submitted dossiers by Ctgb assessors with a focus on the identification of and consistency in dealing with gaps, ambiguities in the assessment framework, data interpretation and conclusions.
  - Board: the contribution and role of the board in the decision making process, in particular the level of competence and procedural aspects.
- The shelf-life for decisions in time and the need for reconsideration of decisions based on
  - developments in EU legislation framework
  - progression in new scientific developments.

Indicators are a.o.:
- Quality:
  - Level of expertise and experience of staff and the Board;
  - Scientific/technical quality of the advisory documents as prepared for the board;
- Process:
  - Documentation and transparency of the advisory and decision making processes;
  - Internal management structure and responsibility levels, consultation and checks and collegial feedbacks;
- Board:
  - Assessment by the board of the advisory documents prepared by the secretariat. Indicators of independence and absence of bias in the decision making process and outcome

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ctgb

The International Visitation Committee (IVC)
The proposed team will include 5 members from different EU-member states with broad experience and expertise in the field of hazard and risk assessment and, jointly, in regulatory authorisation of pesticides and biocides. Committee members will be independent specialists of unbiased reputation, with broad working experience in the public sector.
The committee will include employees or recently retired employees from other EU authorisation bodies.
The international visitation committee will be established and chaired by Herman Koëter (CV attached)

Procedure
The IVC members will be given unlimited access to all documents. Where relevant, the committee is free to speak with people outside Ctgb. Committee members are bound to confidentiality and will sign a formal statement of commitment to full discretion with respect to confidential information of, or in control of, the Board for the authorization of plant protection products and biocides and its associated Secretariat.
After delivery of the draft report, Ctgb is given the opportunity to indicate factual inaccuracies. In case of divergences between Ctgb and the international visitation committee on observations included in the report which are considered by the Board or Ctgb management as inaccurate, Ctgb will be entitled to attach a statement on their position to the report.

Timetable
Based on the request of Ctgb to receive the committee's final report before summer 2013, the following timetable will apply with the provisos that: (i) the international visitation committee (IVC) can be establishment before mid January 2013, (ii) that agreement on the Terms of Reference will be achieved before 21st December 2012 and (iii) that all existing documents on protocols, procedures, criteria, internal compliance monitoring and other issues relevant for the IVC, where possible translated into English, will have been made available to the IVC by the end of January 2013.

The committee is provisionally scheduled to meet on 4 occasions (highlighted in table as bold text) in January, early April, mid May (visitation mission) and early June (draft report). In case of need, the IVC will meet in between these dates by tele/video conference. Dates will be confirmed following the establishment of the IVC .

Date	Milestone
9 Jan 2013	Agreement on ToR
late Jan 2013	**Inaugural meeting of the international visitation committee with Ctgb management**
1 Mar 2013	Delivery work plan by international visitation committee. Work plan indicates methodology and approach for the evaluation, including research questions and indicators.
Mar 2013	Internal discussions within the Ctgb about possible internal actions in preparation for the visitation, largely based on the set of questions considered by the IVC

ctgb

Apr 2013	Delivery of the final work plan, taking into considerations possible suggestions and clarifications by the Ctgb followed by **Consultation meeting of the international visitation committee with the Ctgb management and members of the Board**
Mid May 2013	**Visitation mission (probably 2 days).**
Early June 2013	Delivery draft report, followed by **Meeting of the Visitation Committee with the Ctgb management to discuss the draft final report.**
21 June 2013	Formal presentation of the report

Wageningen,

9 Januari 2013,

Dhr. dr. H.B.W.M. Koëter

.....

dhr. ir. J.F. de Leeuw

.....

Appendix 2

Curriculum Vitae of the Members of the IVC

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

europass

Europass Curriculum Vitae

Personal information

First name(s) / Surname(s)	**Herman B.W.M. Koëter**
Address(es)	83, Kampendaal, B-1653, Dworp, Belgium
Telephone(s)	+32 23045903 (office) Mobile: +32 474190077 (personal)
Fax(es)	
E-mail	Herman.koeter@orangeOhouse.eu (work) herman.koeter@gmail.com (private)
Nationality	Netherlands
Date of birth	1 October 1947
Gender	male

Work experience

Dates	**January 2009 - ongoing**
Occupation or position held	Founder and Managing Director
Main activities and responsibilities	My activities as Managing Director include: • The overall management of the organisation (financial, staff/experts, acquisition, communication, projects and activities, cooperation with other organisations); • Development of basic and advanced training courses in: (i) general toxicology and risk assessment, (ii) the Globally Harmonised System for Classification and Labelling of chemical substances and mixtures (GHS, CLP), (iii) safety assessment of food and food ingredients/contaminants, (iv) animal health and welfare, food-borne diseases, biological hazards, (v) compliance monitoring, and (vi) chemical and food risk management (including exposure assessment, risk reduction and risk communication, emerging risks identification, preparedness and response to food incidents). • Chairing of and lecturing at most training courses provided by OHP; • Establishing Memorandums of Understanding (MOU's) with partner organisations such as UNITAR, GAIN, University faculties; • Assisting the public sector (largely at government level) with advice (both *ad hoc* and as projects) on chemical and food safety, as example: providing the Ministry of Environment in South Africa on the risk management of chemical wastes); • Assisting the private sector (occasionally) on the development of dossiers supporting the authorisation of food, food ingredients and food supplements.
Name and address of employer	Orange House Partnership Management Board, Rond Point Schuman 9, B-1040 Brussels, Belgium

Type of business or sector	**Orange House Partnership (OHP)** is a non-profit partnership organization providing scientific expertise, assistance, advice, and training the areas of food and chemical safety and management to the public and, occasionally, private sector primarily in developing countries and emerging economies. The Partnership consists of approximately 160 international senior experts in risk assessment and risk management with governmental, academic and private sector backgrounds who are passionate about sharing their expertise and experience with professionals in countries with limited access to such sources of knowledge.
Dates	**January 2008 – November 2008**
Occupation or position held	Special Adviser to the Executive Director of the European Food safety Authority (EFSA)
Main activities and responsibilities	I provide high level policy and strategic advice on all issues related to the mission of the Authority. Emphasis is on science policy and interplay between the Commission, EU Member States, NGO's and other stakeholders and the Authority. I provide guidance on scientific approaches to the Heads of Science Units and Technical Support Units and ensure that animal welfare remains high on the agenda of EFSA. Furthermore, I advise on defining new scientific projects and, as needed, provide the terms of reference for these projects. I replace the Executive Director as appropriate and expand and maintain a comprehensive network of experts and policy makers in the area of human health and environmental safety with emphasis on chemical and food/feed safety, environmental risk assessment, and animal health and welfare policies. In this position I manage only a small staff of personal assistants.
Name and address of employer	European Food safety Authority (EFSA), Largo N.Palli 5/A, I-43100 Parma, Italy
Type of business or sector	EU Agency (public sector)
Dates	**October 2003 – September 2005 and July 2006 – December 2007**
Occupation or position held	Deputy Executive Director and Director of Science of the European Food Safety Authority (EFSA)
Main activities and responsibilities	I was responsible for establishing and structuring the Science Directorate, the scientific output, staff and budget management, the move of EFSA from Brussels to Parma and for establishing good working relationships with Member States. I was also responsible for the expansion, functioning, scientific quality and output of the Science Directorate. I established the concept of 'self-tasking' and initiated a pro-active animal welfare policy in EFSA, raising awareness among all regulatory scientists of options to be considered as alternative methods to animal testing and providing Scientific Panels with an educative role in this respect *vis-à-vis* the scientific community at large. Furthermore I replaced the Executive Director as needed and appeared, together with the Executive Director, before the European Parliament. I established a comprehensive network of experts and policy makers in the area of human health and environmental safety with emphasis on chemical and food/feed safety, environmental risk assessment, and animal health and welfare policies. In this position I managed initially (2003) a staff of approximately 30 which grew over the years to close to 200 academic and high level administrative support staff by the end of 2007. The budget I was responsible for grew from €6 million in 2003 to €35 million in 2007 (ABB= activity-based budgeting).
Name and address of employer	European Food safety Authority (EFSA), Largo N.Palli 5/A, I-43100 Parma, Italy
Type of business or sector	EU Agency (public sector)
Dates	**September 2005 – July 2006**
Occupation or position held	Acting Executive Director of the European Food Safety Authority (EFSA)

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Main activities and responsibilities	During the 10 months period between the resignation of the first Executive Director and the appointment of the second Executive Director I was responsible for the operation of the European Food Safety Authority (EFSA) and the execution of its mission and tasks including its management, human resources, growth, output and global positioning. I gave direction to EFSA's role and visibility on the global food and feed safety platform, firmly established its independence from the European Commission and built close relationships with the national food and feed authorities in the US, Canada, Japan, Australia and New Zealand and with a number of international organisations including FAO, OIE, WHO, OECD and Codex Alimentarius. I secured an increasing volume of scientific output which could stand every level of scrutiny. In this position I managed a staff of approximately 180 in 2005 which grew to about 240 in 2006. The budget I was responsible for was close to €60 million.
Name and address of employer	European Food safety Authority (EFSA), Largo N.Palli 5/A, I-43100 Parma, Italy
Type of business or sector	EU Agency (public sector)
Dates	**November 1991 – October 2003**
Occupation or position held	Principal Administrator, Environment, Health and Safety Division, OECD
Main activities and responsibilities	I was responsible for the following international programmes of work aiming towards reaching full consensus: (i) the Programme on Harmonisation of Risk Assessment Policies and Approaches, (ii) the Test Guidelines Programme, (iii) the Programme on International Harmonization of Classification and Labelling of Chemicals, (iv) the Special Activity on Endocrine Disrupters, and (v) the Special Activity on Animal Welfare Policies. Each of these programmes involved substantial numbers of technical and policy experts in OECD member countries, stakeholders and international organisations. The work included chairing numerous expert and policy meetings, drafting annual workplans, progress reports and strategic/policy papers, overseeing the drafting by experts of technical documents, and managing the staff and budget allocated to the respective programmes. I managed to achieve formal OECD recognition of a coalition of national and international animal welfare organisations united in ICAPO (International Council for Animal Protection in OECD Programmes) as NGO, allowing participation in all technical meetings. I also managed to achieve OECD member countries consensus on a hazard classification system for chemical substances and mixtures, and, following this, established under UN.ECOSOC a Working Party of OECD, UN.CETDG, UNITAR, UNIDO, UNEP, WHO, ILO and FAO to develop the GHS (Global Harmonised System for the Classification and Labelling of Chemical Substances and Mixtures) which was adopted by the UN in 2003. In my position of Principal Administrator I managed approximately 20 academic and high level administrative support staff in house and several thousands of external experts. The budget I was responsible for increased from approximately €1 in 1991 to approximately €5 million in 2003 (excluding OECD overhead costs).
Name and address of employer	Organisation for Economic Cooperation and Development (OECD), 2, Rue Andre Pascal, F-75775 Paris, France
Type of business or sector	International Organisation (public sector)
Dates	**August 1967 – November 1991**
Occupation or position held	Several positions held: 1986 – 1991: Associate Head, Department of Biological Toxicology (group of 85-95 academic, technical and administrative support staff) 1984 – 1991: Head, TNO Japan Research Coordination Office (group of 3 academic and 1 administrative support staff) 1981 – 1986: Head of Section of the Department of Biological Toxicology (group of 10-15 academic and technical staff) 1973 – 1981: Head of Subsection of the Department of Biological Toxicology (group of 6-10 academic and technical staff) 1967 – 1973: laboratory assistant and, later, group leader

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Main activities and responsibilities	I starting as laboratory assistant in my pre-academic years and my activities and responsibilities grew over the years following completion of my academic studies (completed in combination with a full time job). I gradually moved from scientific bench work to science management, later followed by positions which could be defined as 'management of science managers'. In my function as TNO Japan Research Coordinator I was responsible for the acquisition and coordination of research projects for TNO in Japan, dealing with a variety of partners (government institutions, universities and private companies) and research areas (including physical chemistry, pharmacology, human (occupational) health, veterinary science, nutrition, pre-clinical and clinical safety assessments). When I left TNO in 1991 I was managing a department of approximately 90 academic, technical and administrative support staff. The department's budget was approximately the equivalent of €6 million.
Name and address of employer	Netherlands Organisation of Applied Scientific Research (TNO), Utrechtseweg 48, 3700 AJ, Zeist, The Netherlands.
Type of business or sector	Not-for-profit research organisation (semi-governmental until the late 1980s)

Education and training

Dates	**1988 (at the establishment of the International Toxicologist Recognition Review System)**
Title of qualification awarded	International Board-certified Toxicologist (ERT)
Principal subjects/occupational skills covered	Occupational health, food/feed safety, chemical risk assessment, animal welfare science
Name and type of organisation providing education and training	National Inter-University Committee for Medical-Biological Research Training, the International Union of National Toxicology Societies (IUTOX) and the European Federation of Toxicology Societies (EUROTOX)
Level in national or international classification	PhD equivalent
Dates	**1980 - 1981**
Title of qualification awarded	Visiting Scientist (Award Letter)
Principal subjects/occupational skills covered	Hazard characterization methodology development based on non-invasive animal behaviour assessments with emphasis on reflex, sensory-motor and cognitive behaviour.
Name and type of organisation providing education and training	Departments of Anatomy and Occupational Health, Medical School, University of Rochester, Rochester, NY, USA
Level in national or international classification	Post-doctoral work
Dates	**1975 – 1983 (on a part-time basis combined with a full-time job)**
Title of qualification awarded	(i) Doctoral degree in Biological Sciences ('Doctorandus' which is MSc/PhD equivalent) *summa cum laude* (ii) College Teacher in Biology (MSc equivalent)
Principal subjects/occupational skills covered	Majors in Biological Toxicology and Experimental Pathology Minors in plant classification
Name and type of organisation providing education and training	State University of Utrecht, Utrecht, The Netherlands
Level in national or international classification	MSc/PhD equivalent Doctor of Toxicology (DTox) (Johns Hopkins University, Baltimore, USA)
Dates	**1967 – 1971 (on a part-time basis combined with a full-time job)**

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Title of qualification awarded	HBO (Higher Vocational Education) Diploma Zoological Engineer (BSc/MSc equivalent) in 1969 Course certificate human pathology (1971) Diploma scientific report writing, documentation and literature review (1972)
Principal subjects/occupational skills covered	Zoology, environmental assessment, histology, microbiology and chemistry
Name and type of organisation providing education and training	Academy for Higher Technical Education (SAL), Utrecht and Amsterdam, The Netherlands
Level in national or international classification	Nationally recognized as Biology Engineer (Ing)

Personal skills and competences

Mother tongue(s): **Dutch**

Other language(s)	Understanding				Speaking				Writing
Self-assessment									
European level (*)	Listening		Reading		Spoken interaction		Spoken production		
English	C2	Proficient user	C2	Proficient user	C2	Proficient user	C2	Proficient user	C2 Proficient user
German	B2	Independent user	B2	Independent user	B1	Independent user	B1	Independent user	A2 Basic user
French	B2	Independent user	B2	Independent user	B1	Independent user	B1	Independent user	A2 Basic user
South African	B1	Independent user	B1	Independent user	A1	Basic user	A1	Basic user	A1 Basic user
Italian	A1	Basic user	A1	Basic user	A1	Very basis user	A1	Very basic user	- No knowledge

(*) Common European Framework of Reference for Languages

Social skills and competences

- **in working environment**: I am considered a good speaker, in particular in explaining rather complicated issues in a way understandable to non-experts. In my functions at EFSA of Acting Executive Director, Deputy Executive Director and Scientific Director I have attended and spoke at numerous social events (dinners, receptions, special performances) at national, regional and community level in the presence of a variety of dignitaries. I practise an open door policy at all times; individual coaching of selected staff, social team-building events including "brown bag" lunches (EFSA), social Friday afternoon drinks(OECD), Friday seminars (Rochester University).
- **in private life**: annual all-staff (and family) cocktail party at my house (EFSA, ca. 200 people), annual social outing for staff (OECD); Boy Scout leader (in the early 1960s), actively involved in humanitarian work through CARE, Terre des Hommes, (Foster Parents) Plan; for many years playing the role of 'St.Nicolas' in kindergartens and elementary schools, and voluntary teacher in open university courses.

Organisational skills and competences

I have developed the organisational and management structure of the Science Directorate in EFSA, which started in 2003 as a team of 15-20 and developed into a Directorate with 2 Departments comprising together 16 Units and more than 200 staff. I was responsible for the move of EFSA from Brussels to Parma, a project that ran for one year.

I was founding member of scientific societies in the Netherlands (society for Critical Review of animal Testing Methods) and at international level [European Research Group on Alternatives for Animal Testing (ERGATT)]. I am the Co-Chair of the organising committee of the 7th World Congress on the Use of Animals in the Life Sciences (Rome, August 2009, 1200 participants, budget: €1.0 Million). I was member of the organising committee of all previous World Congresses on the use of animals

I have (co)organized a large number of international congresses, conferences, many workshops and meetings. I have once, long time ago, set up my own Laboratory for Histological Techniques (LHT) and produced histological slides for biology microscopy practice classes in high schools (1970 -1971).

In my private life I have revitalised the Parent Committee of the International School of Paris (Lycee International in Saint Germain-en-Laye), France of which I was initially treasurer and later Chairman.

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Technical skills and competences	I have introduced a scientific and technical quality control system (Good Laboratory Practice, GLP) in TNO in the 1980s, including compliance, monitoring and standard operating procedures. Privately, I am no more than the 'handyman' at home.
Computer skills and competences	Experienced with the regular desk-top programmes including Word, PowerPoint, Microsoft Outlook and Excel. Skills were acquired over the years by practical experience and a few courses.
Artistic skills and competences	Amateur photographer (only one price in 40-plus years of photography). I am a lover (and collector) of contemporary and fauvist-like art (paintings, sculptures) and music (opera, Mozart, Chopin, Pink Floyd, Genesis, Mark Knopfler, Crosby, Stills, Nash and Young, the Beatles, James Blunt, Scissor Sisters and many others)
Other skills and competences	Hiking, swimming, bicycling
Driving licence	Category A and B (French licence)

Additional information

I have received the following science awards:

- In 1999, the Johns Hopkins University Center for Alternatives to Animal Testing (CAAT) Recognition Award,
- In 2005 the Doerenkamp-Zbinden Prize in acknowledgement of international achievements in the area of animal welfare

I am member of several committees including the following:

- Editorial Board of the scientific journal ATLA (1993 ongoing)
- Dutch government advisory council on animal studies (1988 – 2008 and 2009 ongoing)
- Advisory Board of the Johns Hopkins University CAAT Center (1995 ongoing)
- Harvard university think-tank Committee on food safety (2005 ongoing)
- Management Boards of number of EU Technology Platforms under the 6th and 7th Framework Programme of DG Research (2004 ongoing)
- Dutch Toxicology Society (NVT) (1971 ongoing)
- European and International Federations of Toxicology Societies (EUROTOX, IUTOX) (1978 ongoing)
- Trustee and Chairman of the Alternatives Congresses Trust (ACT) (2008 ongoing) (Chair since 2013)

I was member of a number of committees including the following:

- WHO-IPCS Steering Committee of the Programme on Harmonization of Risk Assessment (1994-2003)
- Founding member and Chairman of the European Research Group on Alternatives to Animal Testing (ERGATT) (think-tank policy group) (1981-1990)
- Dutch Health Council, Advisory Committee on Teratology (1982-1985)
- European Teratology Society (1982-1991, Council member from 1984-1986)
- Japanese Teratology Society (1986-1991)
- Neurobehavioural Teratology Society, USA (1984-1991)
- Teratology Society (1981-1991)
- Advisory Board of the Doerenkamp-Zbinden Foundation (life sciences research support) (2005 ongoing)

I have developed (in my years as bench-working scientist) an alternative for the eye irritation test. In addition, I have an interest in developmental work in Africa, in particular Sudan, South Sudan, Cameroon.

Annexes List of Publications

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

MOST RECENT 2 PAGES OF PUBLICATIONS OUT OF A TOTAL OF MORE THAN 100

Eskes C., Detappe V., **Koëter H.B.W.M.**, Kreysa J., Liebsch M., Zuang V., Amcoff P., et al. (2012). Regulatory assessment of in vitro skin corrosion and irritation data within the European framework: Workshop recommendations. Reg. Tox. Pharmacol. 62:393-403.

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Koëter H.B.W.M., Blijleven W.G., Dreef – van der Meulen H.C., Zielhuis R.L. and Stijkel A. (1989). Adverse effects of pentachlorophenol on fertility and reproduction; a literature study (in Dutch). Directorate General of Labour; Ministry of Social Affairs and Labour of the Netherlands, S73-5 (12 p.), October 1989.

Dreef – van der Meulen H.C., **Koëter H.B.W.M.**, Zielhuis R.L. and Stijkel A. (1989). Adverse effects of Lindane on fertility and reproduction; a literature survey (in Dutch). Directorate General of Labour; Ministry of Social Affairs and Labour of the Netherlands, S73-4 (28 p.), October 1989.

Koëter H.B.W.M., Dreef – van der Meulen H.C., Zielhuis R.L. and Stijkel A. (1989). Adverse effects of 2,4-D and 2,4,5-T on fertility and reproduction; a literature survey (in Dutch). Directorate General of Labour; Ministry of Social Affairs and Labour of the Netherlands, S73-3 (54 p.), October 1989.

Koëter H.B.W.M., Dreef – van der Meulen H.C., Zielhuis R.L. and Stijkel A. (1989). Adverse effects of Dieldrin on fertility and reproduction; a literature survey (in Dutch). Directorate General of Labour; Ministry of Social Affairs and Labour of the Netherlands, S73-2 (76 p.), October 1989.

Dreef – van der Meulen H.C., **Koëter H.B.W.M.**, Zielhuis R.L. and Stijkel A. (1989). Adverse effects of polychlorobifenyls on fertility and reproduction; a literature survey (in Dutch). Directorate General of Labour; Ministry of Social Affairs and Labour of the Netherlands, S73-1 (76 p.), October 1989.

Koëter H.B.W.M., Dreef – van der Meulen H.C., Zielhuis R.L., Stijkel A. and Blijleven W.G. (1989). Adverse effects of industrial chemicals on fertility and reproduction; general considerations and a summary of literature studies of chemical compounds (in Dutch). Directorate General of Labour; Ministry of Social Affairs and Labour of the Netherlands, S73-0 (117 p.), October 1989.

Koëter H.B.W.M. (1988). Behavioural teratology of exogenous substances: regulation aspects. Prog. Brain Res. 73: 59-67.

Bol J., **Koëter H.B.W.M.** and Feron V.J. (1988). Toxicological evaluation of biotechnological products (in Dutch). Voeding 49: 196-198.

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

CURRICULUM VITAE

1. **Family name:** **Autio**
2. **First names:** **Sari Päivikki**
3. **Date of birth:** **31.08.1961**
4. **Nationality:** **Finnish**
5. **Civil status:** **Married, 2 children (1993 and 1995)**
6. **Contact details:** **Finnish Safety and Chemicals Agency Tukes,**
   PO Box 66 (Opastinsilta 12 B), FI-00521 Helsinki, Finland.
   Mobile tel. +358 29 5052 026, e-mail sari.autio@tukes.fi
7. **Education:**

Institution [Date from - Date to]	Degree(s) or Diploma(s) obtained:
University of Helsinki Faculty of Agriculture and Forestry Institute of Environmental Science 09/1981 – 04/1988	Master of Science, Environmental Science

8. **Language skills:** Indicate competence on a scale of 1 to 5 (5 - excellent; 1 - basic)

Language	Reading	Speaking	Writing
Finnish (mother tongue)	5	5	5
Swedish (2nd official language)	4	4	4
English	4	4	4
German	3	3	3

9. **Membership of professional bodies and working groups:**
Member of the Finnish Society of Environmental Sciences

10. **Other skills:** Project management skills. Normal computer skills (Microsoft Windows XP including normal Office 2003 programs like Word, Excel, Powerpoint, Outlook etc.), internal IT-Examination within the Finnish Environment Institute.

Curriculum vitae

Experience on using the FOCUS models and scenarios for ground water and surface water risk assessment of plant protection products. Interest on environmental risk indicators of chemicals.

11. Present position: Senior Adviser, Finnish Safety and Chemicals Agency Tukes, Plant Protection Products Unit, since 1.1.2011. Prior to this organisation, I worked for the Finnish Environment Institute, Chemicals Division, as Senior Adviser since 1990. The change was due to the re-organisation of the chemicals product surveillance authorities in Finland.

12. Key qualifications: About 25 years experience on environmental fate and ecotoxicological risk assessment of plant protection products, administrative tasks and authorization work of plant protection products both at national and international level. Experience on several research and development projects within the field of environmental effects of pesticides in Northern conditions. About five years experience on leading the PPP-team within the FEI. About two years experience as project coordinator within the Pilot project on Biocides funded by the Commission DG ENV. I have been involved with the international cooperation in the decision making within the DG SANCO Standing Committee on Food Chain and Animal Health, EFSA peer review of risk assessments prepared by other MS, OECD Pesticides WG and Nordic co-operation under the Nordic Chemicals Group financed by the Nordic Council of Ministers.

During the preparation of PPP regulation, framework directive of sustainable use of pesticides and pesticide statistics regulation, I was involved with the negotiations in the Council working group. I also participated in preparation of the National Action Plan for reducing the risks of Plant Protection Products in Finland (http://www.mmm.fi/attachments/mmm/julkaisut/tyoryhmamuistiot/newfolder_25/647YNG83G/Trm2011_4_en.pdf) and currently participate in the implementation of it.

In 2012 I was chairing the Northern Zonal Steering Committee for evaluation of PPP, and in 2013 I am supporting the Latvian chairperson as co-chair. The plant protection products will be evaluated within the three zones of the EU and the zonal steering committee manages the workload between the member states.

Since 2010 I am participating the PesticideLife project partly funded by EU LIFE+. The aim of the project is to support the targets of the National Action Plan in reduction of environmental risks from the use of plant protection products and in transition to Integrated Pest Management (IPM) in cereal cultivation. More information about the PesticideLife project is available at: https://portal.mtt.fi/portal/page/portal/mtt_en/projects/pesticidelife .

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Curriculum vitae

13. Professional experience

Date from - Date to	Location	Institute	Position	Description
1/2011 - currently	Helsinki	Finnish Safety and Chemicals Agency Tukes, Plant Protection Products Unit	Senior Adviser	Environmental fate and ecotoxicological risk assessment of plant protection products; administrative work regarding authorization of the products; tasks related to preparing national and EU-legislation on PPP; international cooperation regarding plant protection products (EU, OECD, Nordic); participating in research and development projects concerning the environmental effects of pesticides in Northern conditions; deputy head of unit The change was due to the re-organisation of chemicals product surveillance authorities in Finland, so the tasks remained mainly unchanged.
09/1990 - 12/2010	Helsinki	Finnish Environment Institute, Chemicals Division (formerly National Board of Waters and Environment, Chemicals Control Unit)	Senior Adviser	Ecotoxicological risk assessment of plant protection products; administrative work regarding authorization of the products; tasks related to preparing national and EU-legislation; international cooperation regarding plant protection products (EU, OECD, Nordic); leading the PPP-team; participating in research and development projects concerning the environmental effects of pesticides in Northern conditions.
7/1988 – 9/1990	Helsinki	Finnish Ministry of the Environment	Researcher	Ecotoxicological risk assessment of plant protection products, administrative work regarding authorization of the products
1985 – 1988	Helsinki	University of Helsinki	Researcher	Ecotoxicological research activities regarding hazardous substances and heavy metals in the environment; participating in the Finnish research program on acidification HAPRO

14. Publications:

Lodenius M. & Autio S. 1987. Elohopea ja kadmium maaperässä – sitoutuminen, vapautuminen ja kulkeutuminen. Ympäristö ja Terveys 1/1987: 31-36

Nuorteva P & al. 1987. Happamoitumisen vaikutus raskasmetallien ja alumiinin liikkuvuuteen metsä- ja järviekosysteemissä. Aquilo ser. Bot. 25 vol II: 122-128.

Autio S. 1987. Metsämaan happamuus ja sienten raskasmetallipitoisuudet. Happamoitumisprojektin tutkimusseminaari 21.-24.4.1987. Esitelmien lyhennelmät. Toim. Anttila P. & Kauppi, P. Ympäristöministeriö ja Maa- ja metsätalousministeriö. S. 78.

Autio S. 1987. The acidity of forest soil and the metal concentrations in fungi. Symposium of the Finnish Project on Acidification (HAPRO) April 21-24.4.1987. Abstracts. Ed. Anttila P. & Kauppi P. Publ. Finnish Ministry of the Environment ser. A 64/1987. P. 67

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Curriculum vitae

Lodenius M. & Autio S. 1987. Happaman sadetuksen vaikutus raskasmetallien siirtymiseen kasvillisuuteen. Happamoitumisprojektin tutkimusseminaari 21.-24.4.1987. Esitelmien lyhennelmät. Toim. Anttila P. & Kauppi, P. Ympäristöministeriö ja Maa- ja metsätalousministeriö. S. 83.

Lodenius M. & Autio S. 1987. Effects of artificial acid precipitation in the uptake of heavy metals in plants. Symposium of the Finnish Project on Acidification (HAPRO) April 21-24.4.1987. Abstracts. Ed. Anttila P. & Kauppi P. Publ. Finnish Ministry of the Environment ser. A 64/1987.

Lodenius M, Seppänen A & Autio S. 1987. Leaching of mercury from peat soil. Chemosphere vol 16/6: 1215-1220.

Lodenius M, Seppänen A & Autio S. 1987. Sorption of mercury in soils with different humus content. Bull. Environ. Contam. Toxicol. 39: 593 – 600.

Lodenius M & Autio S. 1989. Effects of Acidification on the mobilization of cadmium and mercury in soils. Arch. Environ. Contam. Toxicol. 18.

Kämäri J. & al 2000. The possible risks of gene technology to the environmental health – the impact of herbicide resistance on the herbicide use in sugar beet cultivation. In: Proceedings SYTTY 2 the Mid-term symposium of the Finnish Research Programme on Environmental Health, 29-30 March 2000. Publication fo the Finnish Research Programme on Environmental Health – SYTTY 1/2000. P. 113-118.

Autio S & al. 2004. Adsorption of sugar beet herbicides to Finnish soils. Chemosphere 55 (2004): 215 – 226.

Autio S & Mecke M. 2008. Torjunta-aineiden toistuvan käytön ympäristöriskien arviointi perunanviljelyssä. Risk assessment of pesticides used consecutively in potato cultivation. Ed. Ruuttunen P. & Laitinen P 2008. Torjunta-aineiden toistuvan käytön ympäristöriskit perunanviljelyssä. Maa- ja elintarviketalous 119:151-177.

Autio, S. & al. 2008. Maatalouden ympäristövaikutukset. Kasvintuotannon ympäristövaikutukset. Ed. Tolonen K & Harmoinen T. 2008. Maatilayrityksen ympäristöopas. P. 13 – 51. Tieto tuottamaan 126. ProAgria Maatalouskeskusten Liitto.

Autio S & al 2009. Hantering av växtodlingens miljörisker. Växtodlingens miljöeffekter. Ed. Tolonen K & Harmoinen K. 2009. Miljöguide för lantbrukare. P. 31 – 56. Forskning för framåt 25. ProAgria Svenska lantbrukssällskapens förbund.

Tiilikkala K & al. 2009. Koivutisleen kaupallistaminen kasvinsuojeluaineeksi ja biosidiksi. Market potential of birch tar oil and registration as biological plant protection products. Ed. Tiilikkala K & Segerstedt M. 2009. Koivutisle – kasvinsuojelun uusi innovaatio. Maa- ja elintarviketalous 143. P.110-129.

Autio S. 2009. Kasvinsuojeluaineiden riski-indikaattoreita yhtenäistetään. Ympäristö 2/2009. P. 26-27.

Koivisto S & Autio S 2009. Kemikaalien ympäristövaikutukset ja riskinarviointi. Ympäristö ja Terveys 7/2009. P. 40 – 45.

Autio S. 2009. Kasvinsuojeluaineiden ympäristöriskien hallinta. Ympäristö ja Terveys 7 /2009. P. 46-47.

Laitinen, P., Junnila S., Markkula, I., Tiilikkala K., Autio S. ja Erlund, P. 2011. Politiikkakatsaus kasvinsuojeluaineiden kestävästä käytöstä. MTT Raportti 20. ISBN 978-952-487-319-2 (verkkojulkaisu), ISBN 978-952-487-320-8 (painettu julkaisu). ISSN 1798-6419. 42 sivua. http://www.mtt.fi/mttraportti/pdf/mttraportti20.pdf

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Curriculum vitae

Autio, S. 2012. Kasvinsuojeluaineiden ympäristöriskien vähentäminen. Ed. Ahvenniemi, P. 2012. Ajankohtaisia kasvinsuojeluohjeita. Kasvinsuojeluseura ry:n julkaisuja 103. ISBN 978-952-5272-62-8. Kariston Kirjapaino Oy, Hämeenlinna 2012. S. 20-22.

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

europass

Europass Curriculum Vitae

Personal information

First name(s) / Surname(s)	**Ursula Anna Lotte Dr. Banasiak**
Address	Federal Institute for Risk Assessment / Max-Dohrn-Str. 8-10, 10589 Berlin (Germany) Since 01 April 2013 retired, Address: Mohrenfalterweg 20, D-14532 Stahnsdorf
Telephone(s)	0049-30-18412-3337
E-mail(s)	Ursula.Banasiak@bfr.bund.de
Nationality	German
Date of birth	22 January 1948
Gender	Female

Work experience

Dates	2005 - 03/2013, since 04/2013 retired
Occupation or position held	Head of Department "Chemical safety"
Name and address of employer	- Federal Institute for Risk Assessment, Berlin, Germany
Dates	2003 - 2005
Occupation or position held	Head of Unit "Residue Assessment of Pesticides and Biocides"
Name and address of employer	- Federal Institute for Risk Assessment, Berlin, Germany
Dates	1991 - 2002
Occupation or position held	Senior scientific counselor / Scientific director
Main activities and responsibilities	Scientist in the Chemistry Division of the Department for Plant Protection Products and Application Techniques of the BBA
Name and address of employer	Federal Biological Research Centre for Agriculture and Forestry, Kleinmachnow, Germany
Dates	1990 - 1991
Occupation or position held	Deputy director of the Institute of Ecological-chemical Research
Name and address of employer	Central Biological Institute, Kleinmachnow, former GDR
Dates	1971 - 1989
Occupation or position held	Scientist
Main activities and responsibilities	Scientist at the Department of Chemical Toxicology Doctor's degree Dr. rerum naturalium, theses rated ‚magna cum laude' Head of laboratories and deputy head of the Department of Ecological Chemistry Head of the Department of Ecological Chemistry
Name and address of employer	Institute of Crop Protection Research, Kleinmachnow, former GDR

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Education and training

Dates	1978
Title of qualification awarded	PhD
Principal subjects / occupational skills covered	Doctor's degree Dr. rerum naturalium, theses rated ‚magna cum laude'
Name and type of organisation providing education and training	- Institute of Crop Protection Research, Kleinmachnow, former GDR
Dates	1966 - 1971
Title of qualification awarded	Chemist
Principal subjects / occupational skills covered	Study of chemistry Diploma of chemistry, rated ‚good'
Name and type of organisation providing education and training	‚Otto von Guericke' Technical University, Magdeburg, former GDR

Personal skills and competences

Mother tongue(s): **German**

Other language(s)

Self-assessment	Understanding				Speaking				Writing	
European level (*)	Listening		Reading		Spoken interaction		Spoken production			
English	B2	Independent user	B2	Independent user	B1	Independent user	B1	Independent user	B1	Independent user

(*) *Common European Framework of Reference (CEF) level*

Additional information

- Member of the FAO Panel of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group (JMPR) since 1993
- Codex Committee on Pesticide Residues since 1995
- Expert in EC- and EFSA working groups on dietary risk assessment

Evaluation of residue data of pesticides in food and feed with regard to the national and European registration process of pesticides, Risk assessment of pesticides residues

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

europass

Europass Curriculum Vitae

Personal information

First name(s) / Surname(s)	**Mark Raymond Lynch**
Address(es)	Glendine, 36 Ludford Drive, Dundrum, Dublin 16, Ireland
Telephone(s)	+353 1 296 4142 Mobile: +353 87 940 1328
Fax(es)	
E-mail	mark@lynchconsulting.ie
Nationality	Irish
Date of birth	27 February 1943
Gender	male

Work experience

Dates	**July 2007 – on-going**
Occupation or position held	Founder and CEO of Lynch Consulting
Main activities and responsibilities	• Management of the organization (financial, communication, projects and activities, cooperation with other organizations) • Development of guidance for the interpretation of the rules concerning proprietary rights to data, relevant arbitration options, confidentiality requirements, rules on minimization of testing using vertebrate species • Assisting the public sector (Inter-government Organizations, Government Departments and Agencies) through advice on both *ad hoc* basis and in the context of particular projects on regulatory issues • Subject to the avoidance of conflicts of interest, assisting the private sector where requested (representative organizations and companies) on the impact of emerging regulatory requirements and on the practical impact of specific regulatory requirements
Name and address of employer	Lynch Consulting, Glendine, 36 Ludford Drive, Dundrum, Dublin 16, Ireland
Type of business or sector	Consultancy Service for Regulatory Authorities, Inter-Government Organizations and Representative Organizations and other stakeholders concerning the regulation of plant protection products, biocides and REACH chemicals Lynch Consulting specializes in strategic, organizational, procedural and other issues for the regulation of plant protection products, biocides and REACH chemicals.

Dates	**March 1995 to July 2007**
Occupation or position held	Head of Service of the Pesticide Control Service, the Irish regulatory authority for pesticides and their residual traces. Staff included 15 Agricultural Inspectors (scientists), 24 Assistant Agriculture Inspectors (scientists), 3 senior Laboratory Technician, 6 Laboratory Technicians, 2 Laboratory Assistants, 6 Senior Field Officers, 4 Field Officers and 1 Clerical assistant). I was responsible for an operational budget of some €5 million.

Main activities and responsibilities	• strategic and operational policy adviser on pesticides to the Minister • development and management of the regulatory system for plant protection and biocidal products (evaluation of active substances; authorization of plant protection and biocidal products; sampling of agricultural produce for residue analysis; inspection and sampling programme for pesticide products and distribution outlets); In that context I championed the system of voluntary mutual recognition and work-sharing for the authorization of plant protection products by Belgium, Ireland, Netherlands and the UK; • as representative of the Minister, delegate to relevant international meetings in the sector (Council of Europe, FAO, WHO, CCPR, EPPO, OECD, European Commission, European Council, NSMC). I was author of 4detailed studies relied upon by the European Commission for the elaboration of Annexes II, III, IV, VI and VI of Directive 91/414/EEC on the placing on the market of plant protection products; As Chairman of the OECD Registration Steering Group, I led the process that developed and published the OECD Vision Document for the Pesticide Regulation Sector and championed the development of the global approach to the evaluation of pesticides, • facilitating and managing inter-institutional research on pesticides, consumer safety and the environment to promote sustainable crop production
Name and address of employer	Department of Agriculture of Agriculture, Food and Forestry, Kildare Street, Dublin 2
Type of business or sector	Government Department
Dates	**June 1974 to March 1997**
Occupation or position held	Pesticide Specialist Department of Agriculture and Food,
Main activities and responsibilities	• initially (1974 to 1978) responsible for developing the regulatory system for pesticides in Ireland, and representing Ireland at relevant international for a (Council of Europe, FAO, WHO, CCPR, EPPO, OECD, European Commission, European Council) • subsequently (1978 to 1995), scientific co-ordinator of the Pesticide Control Service, with particular responsibility for international regulatory matters; I developed the voluntary system for the registration of pesticides that was launched in 1978 and subsequently developed a statutory control system for pesticides introduced in 1985
Name and address of employer	Department of Agriculture of Agriculture and Food, Kildare Street, Dublin 2
Type of business or sector	Government Department
Dates	**September 1973 to June 1974**
Occupation or position held	College Lecturer, Department of Agricultural Botany, Faculty of Agriculture, University College Dublin
Main activities and responsibilities	Lecturing in the fields of plant growth and development and Weed Science to 3rd and 4th year and postgraduate students
Name and address of employer	Faculty of Agriculture, University College Dublin, Albert College, Glasnevin, Dublin 7
Type of business or sector	Public Sector University
Dates	**July 1972 to September 1973**
Occupation or position held	Assistant Inspector, Horticulture Group
Main activities and responsibilities	• teaching agricultural botany to agricultural college students (diploma students) • development of an accounting manual for horticultural enterprises
Name and address of employer	Department of Agriculture and Fisheries, Kildare Street, Dublin 2
Type of business or sector	Government Department
Dates	**September 1971 to July 1972**
Occupation or position held	Research Fellow, Department of Agricultural Botany, Faculty of Agriculture, University College Dublin
Main activities and responsibilities	• Lecturing in the fields of plant growth and development to 3rd and 4th year and postgraduate students • Development of a proposal for research funding in the field of weed science
Name and address of employer	Faculty of Agriculture, University College Dublin, Albert College, Glasnevin, Dublin 7

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Type of business or sector	Public Sector University
Dates	**September 1967 to July 1971**
Occupation or position held	Research Fellow, Department of Vegetable Crops, Cornell University
Main activities and responsibilities	• Post graduate student • Research on synergistic interactions between ultra-low doses of herbicides applied with an oil based spray adjuvant • Research on the mechanism of selectivity and mode of action of the herbicide diphenamid (Thesis Project)
Name and address of employer	Department of Vegetable Crops, Cornell University, Ithaca, NY
Type of business or sector	Land Grand University (Public Sector University)
Dates	**October 1966 to July 1967**
Occupation or position held	Graduate Assistant, Department of Horticulture, The Agricultural Institute
Main activities and responsibilities	• Evaluation of the nutritional requirements of a wide range of bedding plants, vegetables and nursery species in peat based growing media • Development of a general purpose peat based growing medium
Name and address of employer	Horticulture Department, Agricultural Institute, Malahide Road, Kinsealy, County Dublin, Ireland
Type of business or sector	Research Instiitute (Public Sector)

Education and training

Dates	**1969 - 1971**
Title of qualification awarded	Doctoral Degree
Principal subjects/occupational skills covered	Plant physiology, biochemistry, organic chemistry, physical biology, selectivity mechanisms and mode of action of herbicides
Name and type of organisation providing education and training	Cornell University Graduate School
Level in national or international classification	PhD
Dates	**1967 - 1969**
Title of qualification awarded	Master of Science Degree
Principal subjects/occupational skills covered	Plant physiology, agronomy, biochemistry; organic chemistry, physical biology weed science,
Name and type of organisation providing education and training	Cornell University, Graduate School
Level in national or international classification	MS
Dates	**1961 - 1966**
Title of qualification awarded	Bachelor of Agricultural Science Degree
Principal subjects/occupational skills covered	Botany, Zoology, Mechanics, Organic Chemistry, Geology, Soil Science, Biochemistry, Plant Pathology, Entomology, Genetics, Statistics, Agronomy, Agricultural Machinery, Economics
Name and type of organisation providing education and training	Faculty of Agriculture, University College Dublin,
Level in national or international classification	BAgrSc

Appendix 2: *Curriculum Vitae* of the Members of the IVC (Continued)

Personal skills and competences	
Mother tongue(s)	**English**
Other language(s)	

Self-assessment	Understanding		Speaking		Writing
European level (*)	Listening	Reading	Spoken interaction	Spoken production	
Irish	Proficient user	Proficient user	Proficient user	Proficient user	Proficient user

(*) Common European Framework of Reference for Languages

Social skills and competences	I am considered a good motivator and manager of people, encouraging all those that report to me, directly or indirectly, recognizing and utilising individual skills. I practise an open door policy take particular care in coaching staff reporting directly to me, ensuring that other staff are properly coached and mentored. I am considered a good speaker, insisting that complex issues are explained in simple terms. I have made presentations at many international as well as local conferences and events
Organisational skills and competences	I developed the organisational and management structure of the Pesticide Control Service (Pesticide Registration and Control Division and Pesticide Residues Division) of the Department of Agriculture, Food and the Marine, beginning in 1975 with a team of 5, developing it into a service with 60+ staff. I was a founder member of the Irish Society of Toxicology. I was rapporteur to several sessions of the Codex Committee on Pesticide Residues (CCPR) I was chairman of EU Council Working Parties dealing with Directive 91/414/EEC on the marketing and use of plant protection products, on various proposals concerning pesticide residues, and other issues, during the various Irish Presidencies of the European Union I was Chairman of the OECD Registration Steering Group from its inception until 2006, and championed the global approach to the evaluation of pesticides
Technical skills and competences	I developed an ethos of scientific excellence in the work of the Pesticide Control Service
Computer skills and competences	I am experienced in use of the usual range of software programmes, Word, PowerPoint, Microsoft Outlook, EXCEL - skills acquired through practical experience and a few courses
Artistic skills and competences	Lover of classical music, especially opera
Other skills and competences	I am a good listener
Driving licence	Category B, M and W (Irish Licence)
Additional information	• I am chairman since 2008 of the Irish Agricultural Supply Industry Standards Limited (IASIS) a not for profit limited company dedicated to the improvement of standards in the distribution, storage and use of pesticides and animal health products in Ireland – www.iasis.ie • I am a councillor of the Irish Society of Toxicology – www.toxicologyireland.com • I am a member of the Institute of Biology of Ireland • I was a member of the Scientific Advisory Committee of the Food Safety Authority of Ireland until retirement in 2007 • I was a member of the Poisons Council a statutory body established by the Minister of Health until retirement in 2007

Annexes

Major documents prepared included annual reports on Residues in Food, published by the Minister for Agriculture. I was lead author on several publications in the OECD series on pesticdes.

I prepared some 4 studies for and used by the Commission in elaborating Council Directive 91/414/EEC on the marketing and use of plant protection products: -

- Study: Development of Uniform Principles in Relation to the Authorization of Plant Protection Products, 1992,
- Study, Concerning the Inclusion of Active Substances in Annex I to Council Directive 91/414/EEC, 1993
- Study, Concerning the Application of Article 10.1 and 10.2 of Directive 91/414/EEC, Incorporating Draft Guidelines and Forms for Applicants and for the Competent Authorities of the Member States (Mutual Recognition of Tests, Studies and Authorizations), 1996
- Study: Criteria and Procedures for Inclusion of Active Substances in Annex I of Council Directive 91/414/EEC, 2000

Family name : SILANO
Personal name: Vittorio
Academic title: University Degree in "Chemistry" (1965) and PhD in Biochemistry" (1971)
Address: Via Antonio Locatelli, n. 5 - 00136 Rome (Italy)
Mobile phone : (0039) 331 2392414;
Home phone and fax: (0039) 06 35498393
e-mail: vittorio.silano@alice.it
Country of citizenship: Italy
Date and place of birth: 11 December 1940; Naples (Italy)
Sex, marital and family status: Male; Married; Two sons;
Knowledge of languages: **English**: excellent; **French**: acceptable; **Spanish**: limited; **Italian**: mother tongue

1. Working Activity in Italy and Current Position:

Vittorio Silano has worked:

- between 1965 and 1986 at the **Italian National Institute of Health** (Istituto Superiore di Sanita) in Rome (Italy), where he was, since 1982, **Director of the Laboratory of Comparative Toxicology and Ecotoxicology;**
- between 1987 and 1989 at the **Italian Ministry of Environment** in Rome (Italy) where he was the **Director General** of the "**Environmental Pollution Prevention and Reclamation Service**"
- and between 1990 and 2007 at the **Italian Ministry of Health,** Rome (Italy) where between **31 July 2003 and 31 December 2007, he was Head of the Department for Innovation.** This Department includes the following General Directorates: General Directorate for Health Research; General Directorate for Drugs and Medical Devices and General Directorate for Organization, Budget and Personnel. Previous **occupations of V.S. at the Ministry of Health of Italy were as follows: (i)** between **6.03.01 and 31.07.2003 Head of the Department for Human Health Protection, Veterinary Public Health and International Relations; (ii)** between **9.03.98 and 5.03.01**, **Director General** for **International Relations and Community Policies**; **(iii) between 28.04.97 and 8.03.98**, **Director General** for **Medicines Evaluation and Pharmaco-vigilance**; **(iv)** betweeen **21.10.96 and 27.04.97**, **Director General** for "**Prevention**" and acting Director General for Medicines Evaluation and Pharmaco-vigilance; **(v)**

between 22.11.95 and 20.10.96, **Director General** for "**Prevention and Drugs**"; and **(vi) between 3.11.89 and 21.11.95**, **Director General for Food Safety and Nutrition**.

- **V. Silano retired from the Italian Ministry of Health on 1st January 2008 at 67 years and, currently, is contract Professor at the II University of Rome (Tor Vergata) School of Medicine .**

2. PARTICIPATION IN THE WORK OF INTERNATIONAL ORGANIZATIONS

2.1 European Communities and other European Union Institutions

2.1.1. **Since July 2012**, Vittorio Silano is member of the **Contaminant Panel** of the European Food Safety Authority

2.1.2. **Between July 2003 and June 2012**, V. Silano has been chairman of the Scientific Committee of the European Food Safety Authority.

2.1.3. **Between 1997 and 2003**, Vittorio Silano has been vice-chairman of the European Commission (D.G. XXIV – SANCO) **Scientific Steering Committee** and between 2001 and 2003, he has been also chairman of the **ad hoc** BSE/TSE Group and of the GBR Peer Group.

2.1.4. **Beteen 1998-and 2007**, Vittorio Silano has represented Italy in the High Level Committee on Public Health and between 1999-2002 he has chaired the **Working Group on "Pharmaceuticals and Public Health"** of the High Level on Public Health.

2.1.5. **During the year 1996**, Vittorio Silano has been a member of the **Medicines Evaluation (CPMP) Scientific Committee** of the European Agency for Medicines Evaluation (EMEA)-

2.1.6. **During the year 1997** and part of the year 1998, Vittorio Silano has been a member of the Management Board of the European Agency for Medicines Evaluation (EMEA).

2.1.7. **From 1979 to 1987**, Vittorio Silano has been member of the **EEC Scientific Committee for Food.** He has been **vice-chairman** of this Committee since 1982 and **chairman** between 1985 and 1987.

2.1.8. **Since 2003**, V. Silano represented Italy in the Herbal Medicinal Products Committee of the EMEA.

2.1.9. **Since 2004**, V. Silano represents Italy in the European Commission High Level Group on health services and medical care and in the European Council High Level Group on the same subject.

2.1.10. **In 2006**, V. Silano has been appointed as chairman of the European Centre for Diseases Control (ECDC) Panel on "Influenza".

2.2 World Health Organization

2.2.1 **In 1982**, Vittorio Silano worked for six months as **consultant in toxicology** for WHO/EURO and currently (since last month of May) he is consultant to WHO/EUREO on "Geographycally-dispersed Offices".

2.2.2 Vittorio Silano has acted as consultant in a number of **UNEP and**

WHO Expert Groups including JECFA (food additives and contaminants) and JMPR (pesticides) and has served as a WHO/EURO assessor in case of chemical disasters and as member of the Programme Advisory Committee of the IPCS (International Programme on Chemical Safety).

2.2.3 **In 1990 and 1991**, Vittorio Silano has served as a member of the WHO/HQ World Commission on "Health and Environment" that has produced the report entitled "**Our planet, our health**".

2.2.4 **Between June 1991 and April 1992**, Vittorio Silano was the **Director of the Rome Division of the WHO European Centre on "Environment and Health**".

2.2.5. **In 2011,** Vittorio Silano chaired a small expert group requested by WHO/EURO to carry out the review of the WHO geographically dispersed offices.

2.3 Organization for the Economic Cooperation and Development

2.3.1 For a number of years, Vittorio Silano has represented Italy in the OECD Chemical Group and Management Committee.

2.3.2 **Between 1982 and 1984**, Vittorio Silano has acted as **chairman** of the Expert Group appointed by OECD to define criteria to set priorities among **existing chemicals for health purposes**.

2.3.3 **In 1985**, Vittorio Silano has been the chairman of the **OECD ad hoc expert meeting on hazard assessment of existing chemicals**.

2.4 Council of Europe

Vittorio Silano has been member of the toxicology experts Committee on **flavourings** between 1979 and 1983 and of the toxicology experts Committee on **cosmetic products** between 1983-1986. He has also authored the Council of Europe report on "**Plants and Plant Ingredients for cosmetic products**".

3. SCIENTIFIC PRODUCTION AND EDITORIAL ACTIVITY

The scientific production of Vittorio Silano consists of more than **260 papers**, mostly published in **international journals, and books** (see the attached list of publications). Vittorio Silano has acted as **member of the editorial board** of the following scientific journals: Food Additives and Contaminants; Plant Food and Human Nutrition; Toxicology and Industrial Health; Ambiente e sicurezza sul lavoro; Toxicology and Ecotoxicology and Environmental safety. Moreover, between 2003 and 2012, V. Silano has been **Editor in chief** of the EFSA Journal

4. SPECIAL RECOGNITIONS

4.1 With the Decree of the President of the Republic of Italy, issued the 4th December **1990**, Vittorio Silano was bestowed the "Gold Medal of Public Health Merit".

4.2 On the 7th February **1992**, Vittorio Silano was appointed by the

Government of France as Officer of the Order of "Agricultural Merit".
4.3 In **1992**, Vittorio Silano received the "Montefredini" award of the National Association of Chemists and Hygienists.
4.4 In **1996,** Vittorio Silano has been bestowed the "Gold Medal" of the "Foyer des Artists" for his achievements in the field of public health.
4.5. In May **2012**, Vittorio Silano received the "Certificate of Recognition" of the European Food Safety Authority for having served for 9 years as chairman of the Scientific Committee of EFSA.

Rome, 18 December 2012

Antoine J.M. CUVILLIER
French national
48 (born 6.10.1964)
Married two children

PROFESSIONAL EXPERIENCE

Since October 2011
INNOVATIVE MEDICINES INITIATIVE, Brussels
Head of Administration and Finance

Responsible, together with the Executive Director, for the management of Executive Office [40 staff, total funding of € 2 billion for the project duration – 2009-2017 under current setting, making it the largest Public Private Partnership in the heath area worldwide]

- Responsible for the management of staff and budget and all support services [Budget, Finance, HR, Information Technology, Legal affairs, Internal controls], ensuring an effective and efficient use of staff and resources, under the supervision of the Governing Board and EU control bodies (European Commission DG Research and Innovation, European Court of Auditors, Commission Internal Audit Service).
- Overseeing the proper implementation of legal framework, including procedural and intellectual property issues.
- Management of controls, audits, complaints and redress procedures.
- Recently elaborated a policy on management of conflicts of interests, taking into account features linked to the nature of the organisation as public private partnership.

February 2009 – October 2011
EUROPEAN MARITIME SAFETY AGENCY, Lisbon
Head of Department Corporate Services

Responsible for managing all support services with 90 staff and € 30 million annual budget
Functional Director responsible for Legal Affairs and Public Procurement, Human Resources, Information Technology.

April 2008 – February 2009
EU MISSION TO GUINEA BISSAU, Bissau
Head of Administration and Finance

Responsible for managing all support services with 30 staff and € 10 million annual budget.
Functional Director responsible for Legal Affairs and Public Procurement, Human Resources, Information Technology, logistics and security matters, in a challenging professional and living environment.

2003-2008
EUROPEAN FOOD SAFETY AUTHORITY, Brussels and Parma
Various functions including Head of Legal Unit (2003-2008), Acting Head of Human Resources and Acting Deputy Executive Director (2005-2006)

As Head of Legal Unit, managed, under the supervision of the Executive Director and the Deputy Executive Director and in close liaison with Scientific Departments and the European Commission (DG SANCO), legal and procedural set up for the operations of Authority.

Managed redress and litigation, including representation before the European Court of Justice.

1994-2003
EUROPEAN MEDICINES AGENCY, London
Administrator responsible for all legal issues and principal advisor to the Executive Director.

Advising on legal and governance issues regarding the set up and consolidation of the EU centralised procedure for the authorisation of innovative medicines, including on such issues as procedural framework and guidance, appointment and management of conflicts of interest for external experts, litigation and redress procedures.
Responsible for the Management Board and institutional relations with European Commission (DG Enterprise), European Court of Auditors, European Ombudsman.

1990 – 1994
Lawyer in private practice, Associate with HYMAN PHELPS McNAMARA (Washington DC) and BUREAU FRANCIS LEFEBVRE (Paris)

Advising clients in European and French business and commercial legal matters and regulatory matters (medicines, medical devices).

EDUCATION

1988 - 1990: Master of International Law (LL.M.)
Washington College of Law, The American University, Washington D.C.

1986-1988: Diploma of the Institute of International Law (I.H.E.I.)
University of Paris – Pantheon Sorbonne

1983-1987: Master of Laws
University of Paris - Nanterre

Appendix 3

Declarations of Interest and of Confidentiality

ORANGE HOUSE
PARTNERSHIP vzw

DECLARATION OF INTEREST FORM

What is an interest and when could an interest become a conflict?

An 'interest' is any professional, intellectual, material, emotional or other personal advantage or gain a person or his immediate (first degree) relatives may have by being involved in a particular activity or by being a member of a defined group. This means that an individual without any 'interests' would hardly be considered of additive value to the activity or group because he is without a vision or personal opinion and without an intellectual or scientific background or interest in the activity at hand.

An 'interest' may become a conflict of interest when the interest would unduly influence the person's position (objectivity) with respect to the subject matter at hand. An obvious conflict of interest exists when the person involved has a clear material gain by the activity at hand. An *apparent* conflict of interest exists when an interest would not necessarily influence the expert but could result in others perceiving the situation as a conflict and therefore questioning the expert's objectivity.

Types of interest

Different types of direct or indirect material or immaterial (in-kind) interests can be envisaged and the list below, which is certainly not exhaustive, is provided for guidance in making the judgement whether a particular interest should be considered a conflict of interest.

- A current proprietary interest in a substance, technology, process in any sense related to the activity or by the group at hand;
- A current material interest (e.g., shares, bonds) in a commercial entity with an interest in the activity or the group at hand;
- A current or recent (last 5 years) employment, consultancy, directorship or other position in any commercial entity which has an interest in the activity or the group at hand;
- Performance of any paid work or research during the last 5 years commissioned by any entity other than a public entity with an interest in the activity or the group at hand;
- Receipt of grant money supporting work or research during the last 5 years from any entity other than a public entity with an interest in the activity or the group at hand;
- An interest in a competing substance, technology or process or an interest in, or association with work for or support by, a commercial entity having a direct competitive interest, must similarly be declared.

Declaration

Considering the above, have you, or any of your first degree family members, any interest in: (i) the activity or project at hand, (ii) the expert group you have been invited to join, or (iii) any item on the agenda of the current meeting, which may be considered as constituting a real, potential or apparent conflict of interest?

ORANGE HOUSE
PARTNERSHIP vzw

~~yes~~ | no — If yes, please provide details of each interest in the box below

Type of interest	Name of entity involved	Who has the interest? (you, relative, what relationship)	Current interest or years ceased

Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

possibly

~~yes~~ | ~~no~~ If yes, please provide details below

I was scientific director of EFSA from 2003-2008 and in that capacity also responsible for the quality of its scientific output, including opinions on biocides and active ingredients of pesticides. My interests were solely of an intellectual nature

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the activity.

H.B.W.M Koëter — Name

Signature

29/01/2013 — Date

Appendix 3: Declarations of Interest and of Confidentiality

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): KOËTER, Hermanus, Bernardus, Wilhelmus Maria

Date and place of birth: 1 oktober 1947, Maartensdijk

Working for: Orange House Partnership

In the position of: Managing Director

Hereby declares

1. that {he/she} is obliged to observe secrecy regarding all confidential information of or managed by the Board for the Authorisation of Plant Protection Products and Biocides and the secretariat associated with it (abbreviated to Ctgb) and any information that {he/she} knows or could suspect is of a confidential nature, such as company data, financial, legal, or technical data, dossier details, or the Ctgb database to which he/she has been granted access within the framework of the agreed work to be performed. Only with prior permission in writing from the director of the Ctgb may such data be provided to third parties.

2. that {he/she} is aware that a breach of this duty of confidentiality, whether during the effective period of the agreement or after its termination, is subject to the sanctions set by law. A breach of {his/her} duty of confidentiality is deemed to have occurred if the person concerned makes known to a third party, directly or indirectly, in any way or form whatsoever, confidential information on or relating to any particulars of the Ctgb or the work concerning or relating to it.

3. that {he/she} is aware that any breach of the duty of confidentiality will result in an immediately payable penalty of €50,000 being imposed on {him/her} without warning or notice of default having to be served; this does not affect the right of Ctgb to require compliance with this declaration, nor does it affect the right of Ctgb to claim full compensation should such compensation amount to more than the aforementioned penalty sum.

4. that {he/she} is aware that upon the termination of {his/her} current tasks, these obligations as accepted by {him/her} within this context remain in force for a period of 15 years, and that {he/she} continues to be subject to the sanctions set by this declaration and by law in the event of a breach of the confidentiality clauses.

.....
(Signature)

...Brussels, 11 February, 2013

(town/city in which signed, date of signature)

ORANGE HOUSE
PARTNERSHIP vzw

DECLARATION OF INTEREST FORM

What is an interest and when could an interest become a conflict?

An 'interest' is any professional, intellectual, material, emotional or other personal advantage or gain a person or his immediate (first degree) relatives may have by being involved in a particular activity or by being a member of a defined group. This means that an individual without any 'interests' would hardly be considered of additive value to the activity or group because he is without a vision or personal opinion and without an intellectual or scientific background or interest in the activity at hand.

An 'interest' may become a conflict of interest when the interest would unduly influence the person's position (objectivity) with respect to the subject matter at hand. An obvious conflict of interest exists when the person involved has a clear material gain by the activity at hand. An *apparent* conflict of interest exists when an interest would not necessarily influence the expert but could result in others perceiving the situation as a conflict and therefore questioning the expert's objectivity.

Types of interest

Different types of direct or indirect material or immaterial (in-kind) interests can be envisaged and the list below, which is certainly not exhaustive, is provided for guidance in making the judgement whether a particular interest should be considered a conflict of interest.

- A current proprietary interest in a substance, technology, process in any sense related to the activity or by the group at hand;
- A current material interest (e.g., shares, bonds) in a commercial entity with an interest in the activity or the group at hand;
- A current or recent (last 5 years) employment, consultancy, directorship or other position in any commercial entity which has an interest in the activity or the group at hand;
- Performance of any paid work or research during the last 5 years commissioned by any entity other than a public entity with an interest in the activity or the group at hand;
- Receipt of grant money supporting work or research during the last 5 years from any entity other than a public entity with an interest in the activity or the group at hand;
- An interest in a competing substance, technology or process or an interest in, or association with work for or support by, a commercial entity having a direct competitive interest, must similarly be declared.

Declaration

Considering the above, have you, or any of your first degree family members, any interest in: (i) the activity or project at hand, (ii) the expert group you have been invited to join, or (iii) any item on the agenda of the current meeting, which may be considered as constituting a real, potential or apparent conflict of interest?

ORANGE HOUSE
PARTNERSHIP vzw

yes / no (no circled) If yes, please provide details of each interest in the box below

Type of interest	Name of entity involved	Who has the interest? (you, relative, what relationship)	Current interest or years ceased

Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

yes / no (no circled) If yes, please provide details below

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the activity.

Sari Autio		8.2.2013
Name	Signature	Date

Appendix 3: Declarations of Interest and of Confidentiality

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): Autio, Sari Päivikki

Date and place of birth: 31.8.1961 in Raahe, Finland

Working for: the Finnish Safety and Chemicals Agency Tukes

In the position of: Senior Adviser

Hereby declares

1. that {he/she} is obliged to observe secrecy regarding all confidential information of or managed by the Board for the Authorisation of Plant Protection Products and Biocides and the secretariat associated with it (abbreviated to Ctgb) and any information that {he/she} knows or could suspect is of a confidential nature, such as company data, financial, legal, or technical data, dossier details, or the Ctgb database to which he/she has been granted access within the framework of the agreed work to be performed. Only with prior permission in writing from the director of the Ctgb may such data be provided to third parties.

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4. that {he/she} is aware that upon the termination of {his/her} current tasks, these obligations as accepted by {him/her} within this context remain in force for a period of 15 years, and that {he/she} continues to be subject to the sanctions set by this declaration and by law in the event of a breach of the confidentiality clauses.

Sari Autio
(Signature)

Helsinki 8.2.2013
(town/city in which signed, date of signature)

ORANGE HOUSE
PARTNERSHIP vzw

DECLARATION OF INTEREST FORM

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Kampendaal 83, B-1653 Dworp (Brussels) Belgium • email: info@orangeOhouse.eu • tel: +32.23045903

ORANGE HOUSE
PARTNERSHIP vzw

~~yes~~ no If yes, please provide details of each interest in the box below

Type of interest	Name of entity involved	Who has the interest? (you, relative, what relationship)	Current interest or years ceased

Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

~~yes~~ no If yes, please provide details below

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the activity.

URSULA BANASIAK Ursula Banasiak 29.01.2013

Name Signature Date

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): **Dr.Banasiak, Ursula Anna Lotte**

Date and place of birth: **22.01.1948 in Langewiesen, Germany**

Working for: **Federal Institute for Risk Assessment, Berlin, retired 01.04.2013**

In the position of: **Head of Department Chemical Safety**

Hereby declares

1. that {he/she} is obliged to observe secrecy regarding all confidential information of or managed by the Board for the Authorisation of Plant Protection Products and Biocides and the secretariat associated with it (abbreviated to Ctgb) and any information that {he/she} knows or could suspect is of a confidential nature, such as company data, financial, legal, or technical data, dossier details, or the Ctgb database to which he/she has been granted access within the framework of the agreed work to be performed. Only with prior permission in writing from the director of the Ctgb may such data be provided to third parties.

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4. that {he/she} is aware that upon the termination of {his/her} current tasks, these obligations as accepted by {him/her} within this context remain in force for a period of 15 years, and that {he/she} continues to be subject to the sanctions set by this declaration and by law in the event of a breach of the confidentiality clauses.

Ursula Banasiak
.....
(Signature)

Berlin, 08.02.2013
(town/city in which signed, date of signature)

ORANGE HOUSE
PARTNERSHIP vzw

DECLARATION OF INTEREST FORM

What is an interest and when could an interest become a conflict?

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- A current or recent (last 5 years) employment, consultancy, directorship or other position in any commercial entity which has an interest in the activity or the group at hand;
- Performance of any paid work or research during the last 5 years commissioned by any entity other than a public entity with an interest in the activity or the group at hand;
- Receipt of grant money supporting work or research during the last 5 years from any entity other than a public entity with an interest in the activity or the group at hand;
- An interest in a competing substance, technology or process or an interest in, or association with work for or support by, a commercial entity having a direct competitive interest, must similarly be declared.

Declaration

Considering the above, have you, or any of your first degree family members, any interest in: (i) the activity or project at hand, (ii) the expert group you have been invited to join, or (iii) any item on the agenda of the current meeting, which may be considered as constituting a real, potential or apparent conflict of interest?

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Appendix 3: Declarations of Interest and of Confidentiality

ORANGE HOUSE PARTNERSHIP vzw

yes	

If yes, please provide details of each interest in the box below

Type of interest	Name of entity involved	Who has the interest? (you, relative, what relationship)	Current interest or years ceased
Consultancy	Lynch Consulting	I have	current
Consultancy	Hume Brophy	I have	current

Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

	no

If yes, please provide details below

Former Head of Pesticide Control Service, Dublin. Former Chairman OECD Pesticide Registeration Steering Group.

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the activity.

Mark R Lynch	Mark R Lynch	1 February 2013
Name	Signature	Date

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): Lynch, Mark R.

Date and place of birth: 27th February 1943, Kilkenny, Ireland

Working for: International Visitation Committee (IVC) for the Evaluation of the Scientific Output of Authorization Decisions of the Netherlands Board for the Authorization of Plant Protection Products and Biocides (Ctbg)

In the position of Committee Member

Hereby declares

1. that he is obliged to observe secrecy regarding all confidential information of or managed by the Board for the Authorisation of Plant Protection Products and Biocides and the secretariat associated with it (abbreviated to Ctgb) and any information that he knows or could suspect is of a confidential nature, such as company data, financial, legal, or technical data, dossier details, or the Ctgb database to which he has been granted access within the framework of the agreed work to be performed. Only with prior permission in writing from the director of the Ctgb may such data be provided to third parties.

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3. that he is aware that any breach of the duty of confidentiality will result in an immediately payable penalty of €50,000 being imposed on him without warning or notice of default having to be served; this does not affect the right of Ctgb to require compliance with this declaration, nor does it affect the right of Ctgb to claim full compensation should such compensation amount to more than the aforementioned penalty sum.

4. that he is aware that upon the termination of his current tasks, these obligations as accepted by him within this context remain in force for a period of 15 years, and that he continues to be subject to the sanctions set by this declaration and by law in the event of a breach of the confidentiality clauses.

.....
(Signature)

Dundrum, Dublin 16, 12th February 2013
(town/city in which signed, date of signature)

ORANGE HOUSE
PARTNERSHIP vzw

DECLARATION OF INTEREST FORM

What is an interest and when could an interest become a conflict?

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- Performance of any paid work or research during the last 5 years commissioned by any entity other than a public entity with an interest in the activity or the group at hand;
- Receipt of grant money supporting work or research during the last 5 years from any entity other than a public entity with an interest in the activity or the group at hand;
- An interest in a competing substance, technology or process or an interest in, or association with work for or support by, a commercial entity having a direct competitive interest, must similarly be declared.

Declaration

Considering the above, have you, or any of your first degree family members, any interest in: (i) the activity or project at hand, (ii) the expert group you have been invited to join, or (iii) any item on the agenda of the current meeting, which may be considered as constituting a real, potential or apparent conflict of interest?

Appendix 3: Declarations of Interest and of Confidentiality

ORANGE HOUSE
PARTNERSHIP vzw

yes | ~~no~~ If yes, please provide details of each interest in the box below

Type of interest	Name of entity involved	Who has the interest? (you, relative, what relationship)	Current interest or years ceased

Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

yes | ~~no~~ If yes, please provide details below

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the activity.

Vittorio SILANO — Name

Signature

1st February 2013 — Date

Appendix 3: Declarations of Interest and of Confidentiality

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): SILANO Vittorio

Date and place of birth: 11 December 1940, NAPLES (ITALY)

Working for: Retired from the Italian Ministry of Health

In the position of: Head of the Department of Innovation

Hereby declares

1. that {he/she} is obliged to observe secrecy regarding all confidential information of or managed by the Board for the Authorisation of Plant Protection Products and Biocides and the secretariat associated with it (abbreviated to Ctgb) and any information that {he/she} knows or could suspect is of a confidential nature, such as company data, financial, legal, or technical data, dossier details, or the Ctgb database to which he/she has been granted access within the framework of the agreed work to be performed. Only with prior permission in writing from the director of the Ctgb may such data be provided to third parties.

2. that {he/she} is aware that a breach of this duty of confidentiality, whether during the effective period of the agreement or after its termination, is subject to the sanctions set by law. A breach of {his/her} duty of confidentiality is deemed to have occurred if the person concerned makes known to a third party, directly or indirectly, in any way or form whatsoever, confidential information on or relating to any particulars of the Ctgb or the work concerning or relating to it.

3. that {he/she} is aware that any breach of the duty of confidentiality will result in an immediately payable penalty of €50,000 being imposed on {him/her} without warning or notice of default having to be served; this does not affect the right of Ctgb to require compliance with this declaration, nor does it affect the right of Ctgb to claim full compensation should such compensation amount to more than the aforementioned penalty sum.

4. that {he/she} is aware that upon the termination of {his/her} current tasks, these obligations as accepted by {him/her} within this context remain in force for a period of 15 years, and that {he/she} continues to be subject to the sanctions set by this declaration and by law in the event of a breach of the confidentiality clauses.

Vittorio Silano
(Signature)

Rome, 15 February 2013
(town/city in which signed, date of signature)

ORANGE HOUSE
PARTNERSHIP vzw

07 FEB 2013

DECLARATION OF INTEREST FORM

What is an interest and when could an interest become a conflict?

An 'interest' is any professional, intellectual, material, emotional or other personal advantage or gain a person or his immediate (first degree) relatives may have by being involved in a particular activity or by being a member of a defined group. This means that an individual without any 'interests' would hardly be considered of additive value to the activity or group because he is without a vision or personal opinion and without an intellectual or scientific background or interest in the activity at hand.

An 'interest' may become a conflict of interest when the interest would unduly influence the person's position (objectivity) with respect to the subject matter at hand. An obvious conflict of interest exists when the person involved has a clear material gain by the activity at hand. An *apparent* conflict of interest exists when an interest would not necessarily influence the expert but could result in others perceiving the situation as a conflict and therefore questioning the expert's objectivity.

Types of interest

Different types of direct or indirect material or immaterial (in-kind) interests can be envisaged and the list below, which is certainly not exhaustive, is provided for guidance in making the judgement whether a particular interest should be considered a conflict of interest.

- A current proprietary interest in a substance, technology, process in any sense related to the activity or by the group at hand;
- A current material interest (e.g., shares, bonds) in a commercial entity with an interest in the activity or the group at hand;
- A current or recent (last 5 years) employment, consultancy, directorship or other position in any commercial entity which has an interest in the activity or the group at hand;
- Performance of any paid work or research during the last 5 years commissioned by any entity other than a public entity with an interest in the activity or the group at hand;
- Receipt of grant money supporting work or research during the last 5 years from any entity other than a public entity with an interest in the activity or the group at hand;
- An interest in a competing substance, technology or process or an interest in, or association with work for or support by, a commercial entity having a direct competitive interest, must similarly be declared.

Declaration

Considering the above, have you, or any of your first degree family members, any interest in: (i) the activity or project at hand, (ii) the expert group you have been invited to join, or (iii) any item on the agenda of the current meeting, which may be considered as constituting a real, potential or apparent conflict of interest?

Appendix 3: Declarations of Interest and of Confidentiality

ORANGE HOUSE
PARTNERSHIP vzw

yes	no

If yes, please provide details of each interest in the box below

Type of interest	Name of entity involved	Who has the interest? (you, relative, what relationship)	Current interest or years ceased

NO INTEREST

Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

yes	no

If yes, please provide details below

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the activity.

A. Cuvillier — Name

Signature

30.01.2013 — Date

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): CUVILLIER Antoine

Date and place of birth:

Working for: ini JU

In the position of: Head of Administration and finance

Hereby declares

1. that {he/she} is obliged to observe secrecy regarding all confidential information of or managed by the Board for the Authorisation of Plant Protection Products and Biocides and the secretariat associated with it (abbreviated to Ctgb) and any information that {he/she} knows or could suspect is of a confidential nature, such as company data, financial, legal, or technical data, dossier details, or the Ctgb database to which he/she has been granted access within the framework of the agreed work to be performed. Only with prior permission in writing from the director of the Ctgb may such data be provided to third parties.

2. that {he/she} is aware that a breach of this duty of confidentiality, whether during the effective period of the agreement or after its termination, is subject to the sanctions set by law. A breach of {his/her} duty of confidentiality is deemed to have occurred if the person concerned makes known to a third party, directly or indirectly, in any way or form whatsoever, confidential information on or relating to any particulars of the Ctgb or the work concerning or relating to it.

3. that {he/she} is aware that any breach of the duty of confidentiality will result in an immediately payable penalty of €50,000 being imposed on {him/her} without warning or notice of default having to be served; this does not affect the right of Ctgb to require compliance with this declaration, nor does it affect the right of Ctgb to claim full compensation should such compensation amount to more than the aforementioned penalty sum.

4. that {he/she} is aware that upon the termination of {his/her} current tasks, these obligations as accepted by {him/her} within this context remain in force for a period of 15 years, and that {he/she} continues to be subject to the sanctions set by this declaration and by law in the event of a breach of the confidentiality clauses.

(Signature)

Brussels, 7.02.2013
(town/city in which signed, date of signature)

Appendix 4

Activity Plan for the Work of the IVC

Establishment of the International Visitation Committee (IVC)

1. At the request of the Chair of the Ctgb Board, in January 2013, an international visitation committee was established by Dr. Herman Koëter which was endorsed by the Board on 24 January. The membership of the IVC is as follows:

a. Dr Sari Autio, TUKES, Finland;
b. Dr Ursula Banasiak, BfR, Germany;
c. Dr Herman Koëter, Orange House Partnership, Belgium (Chair)
d. Dr Mark Lynch, Lynch Consulting, Ireland;
e. Dr Vittorio Silano, 2nd University of Rome, Italy

The inaugural meeting of the IVC was held at the Ctgb on 1 February 2013: a joint morning session of the IVC and the Chair of the Ctgb Board and senior Ctgb management, followed by a closed afternoon session of the IVC.

2. The assignment of the IVC is detailed in the Terms of Reference, agreed between the Ctgb Board and the Chair of the IVC on 9 January 2013. The objective and scope of the visitation is to assess the independence, the scientific quality and the legal compliance with EU and national regulations of the formal risk assessment and decision making processes and related outputs of the Ctgb following requests for the authorisation of plant protection products and biocides in the Netherlands. The aim of the present activity is to provide: (i) a reliable, independent and internationally oriented assessment of the current quality of formal Decisions in light of current state-of-the-art science and legal requirements and, (ii) suggestions and advice, as appropriate, on possible improvements to ensure independent and high quality outputs of the Ctgb.

Evaluation of the Scientific Process

3. The evaluation of the quality of the scientific process will be based on three main aspects: (i) the availability of and adherence to up-to-date guidance documents concerning the scientific process, (ii) the clarity, degree of insight and extent of coverage of the scientific process provided by the guidance documents and (iii) the assessment of the scientific process as such. The following steps are identified:

a. Evaluation of the availability and accessibility of the documentation provided;
b. Identification of gaps in the scientific process descriptions;
c. Assessment of the use in practice of and adherence to the documentation covering the scientific process;
d. In depth evaluation of the scientific process applying a series of quality indicators as described below.

Evaluation of the Scientific Output

4. Evaluation of the quality of the scientific output will be is based on: (i) the quality of the scientific staff involved, (ii) the opportunities for scientific staff to keep up with new

scientific developments and insights, and (iii) the quality of scientific evidence, and the level of clarity, transparency, and intelligibility of scientific outputs of the Ctgb. Outputs include: Decisions, Draft Assessment Reports, scientific articles, lectures, etc. The following steps in the assessment of the quality of scientific output are identified:

a. The level of expertise and experience of the scientific staff in the area of pesticide and/or biocide risk assessment;
b. The working environment (e.g., work pressure, structural arrangement for keeping up with new developments);
c. In depth evaluation of the scientific output by:
    i. Scrutinizing a random as well as specific selection of Decisions on Draft Assessment Reports (DAR) of active substances for EU approval, plant protection products for national and zonal approval, and biocides, applying a series of quality indicators as described below;
    ii. Scrutinizing other types of scientific output such as lectures at scientific symposia, congresses, etc., scientific publications, guidance documents, rebuttals, etc. against the same criteria.

5. Evaluation of each of the selected outputs will be done by all members of the IVC individually, applying a common grading system, followed by sharing and comparing evaluations and reaching a common IVC opinion on the scientific quality of each of the defined outputs.

Evaluation of the Decision-making Process of the Board

6. The IVC will carefully review the decision-making process and other responsibilities and/or authorizing capacities of the Board with emphasis on risk assessment and risk management elements. In its evaluation of the quality of the Board's decision-making process, the Committee will apply the criteria a set out in paragraph 7.3 below.

Development of Indicators

7. A series of (semi)quantitative quality indicators have been developed by the IVC for the evaluation of: (i) the scientific process, (ii) the scientific outcome and (iii) the decision-making process by the Board. The indicators agreed upon are as follows:

7.1 Indicators of the quality of the scientific process

a. Level of transparency of the scientific process, including procedures for work-sharing, outsourcing of evaluations, and mutual recognition of assessment reports.
b. Level of quality (expertise, experience, work history) of scientific staff at the time of recruitment and Ctgb policies to ensure scientific quality would not fall behind with developments in science.
c. Frequency of involvement/consultation of external scientific experts (as a routine or occasional procedure) and their level of expertise, experience and work history).
d. Staff turnover (high/low), number of vacant posts and average number of applicants to vacant posts for scientific staff.

e. Evidence of continuous education and training of scientific staff (e.g., congresses, lectures, training courses).
f. Level of pressure on the scientific staff resulting from workload and related legal deadlines.
g. Level of compliance with the adopted risk assessment methodologies.
h. Evidence of external and of routine internal peer reviews of scientific output.
i. Evidence of peer review by Ctgb of relevant evaluations conducted by other Member States that are relied upon for risk assessments submitted to the Board for authorization decisions
j. Level of detail of the peer reviews, and the reviewers' findings
k. Proof of independence of scientific staff and scientific team-leaders vis-à-vis the Ctgb Board, the dossier owners, governmental authorities and public interest groups.
l. Proof of independence of Board members with respect to the scientific risk assessment output and subsequent risk management recommendations (separation of risk assessment and risk management).
m. Level of legal compliance with national and EU legislation.

7.2 Indicators of the quality of the scientific output

a. Evidence of the state-of-the-art level of knowledge and quality of the scientific staff (e.g., by records of continuous education: post-graduate and refresher courses, attendance of scientific conferences, lectures, publications, invitations, etc.).
b. Evidence of appreciated scientific contributions by scientific staff to international risk assessment bodies, such as the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), Codex Alimentarius (Sub)Committees, The OECD Working Group on Pesticides, the European Food Safety Authority (EFSA), the European Chemicals Bureau (ECB), etc.
c. Quality of the adopted risk assessment methodologies (state-of-the-art science, sufficiently detailed, covering all relevant issues) and confirmation of compliance of the Decisions with the adopted methodologies.
d. Clarity and comprehensibility of the Decisions and other scientific outputs especially in terms of data available, data utilized, methodology applied in the assessment, weight of evidence considerations, variability and uncertainties and assumptions, conclusions and recommendations.
e. Quality of collegial feedback and peer reviews (do findings affect procedures, approaches, interpretations?)
f. Level of consistency and coherence of scientific evaluations.
g. Level of recognition and acceptance of Ctgb Decisions on active PPP substances and biocides (complete dossiers) by EFSA and competent authorities in member states.
h. Level of recognition and acceptance of Ctgb Decisions on pesticide preparations by EU member states in the same zone (where Ctgb was the Rapporteur for the zone).
i. Outcome of the reviews by the IVC of adopted Decisions on PPP and biocide preparations, selected by choice (based on minutes of the Ctgb Board and delivery time) as well as randomly.
j. Outcome of the reviews by the IVC of adopted Decisions on PPP and biocidal active substances, selected by choice (based on minutes of the Ctgb Board and delivery time)as well as randomly.

7.3 Indicators of the quality of the Board's decision-making process

a. The extent to which the technical profiles of the individual Board members and of the Board as a whole fits with its risk management tasks.
b. Proof of independence of the Board members with respect to the consequences of the Decisions they adopt.
c. The level of attendance of Board members to Board meetings.
d. The frequency of Board meetings and workload of the Board.
e. The rate of Decisions made by consensus by the full Board as compared to Decisions made by majority voting or by a subset of the Board.
f. The relevance of criteria defined and applied by the Board to assess the acceptance or rejection of a Draft Decision.
g. The level of detail of the minutes/reports of Board discussions of Draft Decisions.
h. The number of appeals and formal complaints by applicants and the adequateness of subsequent rebuttals
i. The number of Draft Decisions not accepted by the Board (and its reasoning) vis-à-vis the total number of Draft decisions presented to the Board.

Documentation and other Information Needed to Carry Out the Assessment of the Scientific Ouptut

8. In order to be able to carry out the scientific assessment as addressed above, a substantial amount of information and documentation is needed from the Ctgb management, the Ctgb Board and, as appropriate, external sources. In addition, interviews with identified Ctgb Board members and staff and, possibly, external individuals are required for a full insight and understanding of scientific processes and assessments.

Requests for Information and Documents Relevant to the Visitation

9. At the inaugural meeting, IVC members present were provided with paper copies and electronic copies (on 4th February) of 4 presentations given by Ctgb as follows:

a. "General Presentation" by Mr de Leeuw, Chairman of the Board,
b. "Board and Secretariat: Organization, Challenges and Qualities" by Mr van Duijn, Director of the Ctgb,
c. "General Presentation of Practical and Scientific Working Procedures" by Mr Pol, Team Manager and
d. "Provision, Access and Storage of Confidential Information" by Mr Kortekaas, Knowledge and Quality Manager.

10. The following list of items, documents and other materials are considered necessary for the evaluation to be undertaken by the Committee:

a. Inventory of and access to all technical, procedural and guidance documents relating to the scientific process that are currently in use.
b. Inventory of and access to legal documents relevant for the work of the Ctgb.

c. Access to documentation on selection and evaluation criteria for use by scientific staff and management, including staff training policies (initial and continuous training), training records and/or files.
d. Detailed organisational chart of scientific staff and management (CVs, descriptions of functions and responsibilities, and identification of critical functions).
e. Access to Declarations of Interest (DOI) of all scientific staff over the last 5 years.
f. Access to reports/documentation on internal and external scientific peer review processes and evaluations.
g. Access to documentation on procedures for dealing with formal complaints by dossier owner(s) and interested third parties and records of how these complains have been addressed, including the history (5 years) of formal appeals.
h. Access to written communication with applicants.
i. Access to documentation on Mutual Agreement (MR) procedures.
j. Access to minutes of meetings of the Ctgb Board and of meetings of the scientific staff (both scientific and procedural).
k. Access to operations manuals and SOPs prepared for use by scientific staff and dossier managers (co-ordinators) (to extent not included in item a).
l. Access to policy and operational guidance prepared for Board members in making management decisions on proposals submitted.

11. The list of requested items was submitted to the Ctgb secretariat on 4 February with the request to provide access to the requested information as soon as possible. Minor additions to the list were submitted to the Secretariat on 15 February (items k and l).

12. By a separate request of 4 February, the following documents were requested: a list of all Decisions of 2012 and 2011 together with: (i) the date of submission, (ii) the dates of acceptance (after the administrative and technical completion checks), (iii) the date of the adoption by the Board of the final Decisions, and (iv) grouped by type of evaluation (pesticide substances for EU approval, pesticide products for national or zone approval and biocides).

Caveat with respect to requested documentation

13. it should be clear that, whereas the IVC considers the above-mentioned requests as relevant for carrying out is evaluation, it is aware that many of the available documents addressing some, or all, the requests listed above may not available in English and that time and budget do not allow for the translation of a substantial number of documents into English. Consequently, the IVC is willing to focus primarily on documents (in English) that the Ctgb management and Board would consider of importance for the work of the ICV in the present context. Any suggestions in this respect would be highly appreciated.

Interviews

14. Interviews with individual staff members of the Ctgb are essential to confirm or correct findings from the dossier and document evaluations or to clarify issues that arise. Dates set for these interviews are 21 and 22 May (see also under Time Schedule. The Committee expects that key scientific staff will make themselves available on those dates. By mid April a list will be provided of the individuals the Committee wishes to interview.

15. The Committee also wishes to speak with the Board members. Provisionally 17 April is earmarked for these interviews (see also under Time Schedule).

Time Schedule

16. The following time schedule was agreed between the Ctgb Board, the Ctgb management and the IVC:

a. 1 February: Inaugural meeting of the IVC with the Ctgb Board and senior staff.

b. As soon as possible following the inaugural meeting: Ctgb to provide access to the IVC members to as much of the already requested documentation as possible.

c. Before the 1st of March 2013: activity plan available for information of the Board and senior management (e.g., methodology and approach of the evaluation, type and level of depth of questions/inquiries, quality indicators). List of additional documents to which access is required.

d. March 2013: based on the work plan and additional document access requests, Ctgb management and Board will start preparing for the visitation, provides access to all requested documentation and arranges for English translations as appropriate.

e. At the latest by the end of March 2013: Ctgb management to provide to the IVC all requested documentation, including those that need translation into English. Ctgb may make comments, as appropriate, on the action plan.

f. Second week of April 2013: final action plan will be made available to the Board and senior management, taking into consideration the possible comments and suggestions made by the Board and senior management.

g. 17 April 2013: Face-to-face meeting of the IVC, including a session with the Board and, as needed, with the senior Ctgb management and/or external individuals. With respect to the latter, as appropriate, the selection of external experts will be done with the consent of the Ctgb Director and Chairman of the Board.

   The meetings on the 17 April should result in a full understanding by the Ctgb of the nature, the level of detail and the extent of the 2-day visitation in May. Full access to all (confidential) documents relevant for the visitation, and of practical needs such as secretarial support, internet access, a private office equipped with a telephone with an open line, a printer/scanner, printer paper and a computer.

h. 21-22 May 2013: a 2-day visitation at the Ctgb.

i. Second week of June 2013: submission (possibly by electronic mail) to the Board and senior Ctgb management of the draft final report of the visitation mission which is likely to be a concise report with annexes.

j. 26 June 2013: Meeting of the IVC with the Board and senior management to discuss the draft final report: further elaboration of issues and findings not (fully) clear to the Ctgb, discussion of possible misunderstandings or apparent mistakes that need correction and other factual discrepancies, if any.

k. 3 July 2013: Formal presentation of the final report to the Board and senior staff by the Chairman of the IVC. Possibly, a press statement or press meeting may be appropriate (to be decided by the Ctgb).

Appendix 5

Evaluation Forms Developed and Used by the IVC

Appendix 5: Evaluation Forms Developed and Used by the IVC (Continued)

I. Evaluation of Professional Qualifications of Ctgb Internal Scientific Staff and External Scientific Consultants

CRITERIA AND COMMENTS
University and post-graduate **Education** **Comments:**
Expertise, experience, work history of scientific staff at the time of recruitment **Comments:**
Duties and main activities at the Ctgb since the time of recruitment (date to be specified) **Comments:**
Evidence of the state-of-the-art level of knowledge and quality of the scientific staff (e.g., by records of continuous education: refresher courses, attendance of scientific conferences, etc.) before and after recruitment by the Ctgb **Comments:**
Evidence of valuable scientific **contributions to the development of risk assessment methodologies** through publications in peer-reviewed journals, lectures, etc. **Comments:**
Evidence of appreciated scientific **contributions by scientific staff to international risk assessment** bodies, such as the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), Codex Alimentarius (Sub)Committees, The OECD Working Group on Pesticides, the European Food Safety Authority (EFSA), the European Chemicals Bureau (ECB), etc **Comments:**
Other criteria: **Comments:**
OVERALL STATEMENT:

Appendix 5: Evaluation Forms Developed and Used by the IVC (Continued)

II. Evaluation of Scientific Process Quality

CRITERIA AND COMMENTS
Staff turnover (high/low), number of vacant posts and average number of applicants to vacant posts for scientific staff **Comments:**
Frequency of **involvement or consultation of external scientific experts** (as a routine or occasional procedure) and their level of expertise, experience and work history **Comments:**
Level of **pressure on the scientific staff** resulting from workload and related legal deadlines **Comments:**
Quality of the adopted **risk assessment methodology** (state-of-the-art science, sufficiently detailed, covering all relevant issues) **Comments:**
Ctgb **policies to ensure scientific quality** would not fall behind with developments in science **Comments:**
Level of **transparency of the scientific process,** including procedures for work-sharing, outsourcing of evaluations, and mutual recognition of assessment reports. **Comments:**
Clarity and comprehensibility of the scientific opinions especially in terms of data available, data utilized, weight of evidence considerations, variability and uncertainties and assumptions, conclusions and recommendations. **Comments:**
Level of **compliance with the adopted risk assessment methodologies** **Comments:**
Level of adequateness of the **response to comments, questions, suggestions of the Board** **Comments:**
Evidence of **external and** of routine **internal peer reviews** of scientific output **Comments:**
Evidence of peer review by Ctgb **of relevant evaluations conducted by other Member States** that are relied upon for risk assessments submitted to the Board for authorization decisions **Comments:**

Appendix 5: Evaluation Forms Developed and Used by the IVC (Continued)

CRITERIA AND COMMENTS
Level of **detail of the peer reviews**, and the reviewers' findings **Comments:**
Proof of **independence of scientific staff** and scientific team-leaders vis-à-vis the Ctgb Board, the dossier owners, governmental authorities and public interest groups **Comments:**
Level of **legal compliance with national and EU legislation** **Comments:**
Other criteria **Comments:**
OVERALL STATEMENT

Appendix 5: Evaluation Forms Developed and Used by the IVC (Continued)

III. Comments on selected product dossiers

Product:
CRITERIA AND COMMENTS
Confirmation of **compliance** of the Decision **with adopted guidance and/or legislation** **Comments:**
Clarity and comprehensibility of the Decision especially in terms of data available, data utilized **Comments:**
Weight of evidence considerations, variability and uncertainties and assumptions, conclusions and recommendations. **Comments:**
Evidence of collegial feedback and/or peer reviews of draft Decisions **Comments:**
Level of adequateness of the **response to comments, questions and suggestions of the Board** **Comments:**
Other criteria **Comments:**
OVERALL STATEMENT;

Appendix 5: Evaluation Forms Developed and Used by the IVC (Continued)

IV. Comments on Selected Draft DARs and CARs Prepared by the Ctgb

Product:
CRITERIA AND COMMENTS
Confirmation of **compliance** of the DAR OR CAR **with legislation and guidance documents available** **Comments:**
Clarity and comprehensibility of the Scientific Opinion especially in terms of data available and data utilized **Comments:**
Weight of evidence considerations, variability and uncertainties and assumptions, conclusions and recommendations **Comments:**
Evidence of collegial feedback and/or peer reviews **Comments:**
Level of **consistency and coherence** of the DAR/CAR with other DARs/CARs **Comments:**
Evidence of **recognition and acceptance of the** DAR or CAR by EFSA, ECB, EU member states **Comments:**
Level of adequateness of the **response to comments, questions and suggestions** from Member States' experts **Comments:**
Other criteria **Comments:**
OVERALL STATEMENT:

V. Evaluation Form for the Overall Management and Decision-making Process of the Board

CRITERIA AND COMMENTS
Time between acceptance of the submission **and the draft Decision** **Comments:**
Time between submission to the Board **and the Boards approval** **Comments:**
Compliance of the decisions with the current legislation (time limits met, number of possible court cases etc.) **Comments:**
The **frequency of Board meetings** and **workload** of the Board. **Comments:**
The rate of **Decisions made by consensus** by the full Board as compared to Decisions made by majority voting or by a subset of the Board **Comments:**
The level of **detail of the minutes/reports** of Board discussions of Draft Decisions **Comments:**
The number of **appeals and formal complaints** by applicants **and the adequateness of subsequent rebuttals** **Comments:**
The number of **Draft Decisions not accepted** by the Board (and its reasoning) vis-à-vis the total number of Draft decisions presented to the Board **Comments:**
Proof of **independence of Board members** with respect to the scientific risk assessment output and subsequent risk management recommendations (separation of risk assessment and risk management) **Comments:**

Appendix 5: Evaluation Forms Developed and Used by the IVC (Continued)

CRITERIA AND COMMENTS
The extent to which the technical **profiles of the individual Board members** and of the Board as a whole fits with its risk management tasks **Comments:**
Proof of **independence of the Board members** with respect to the consequences of the Decisions they adopt. **Comments:**
The **level of attendance** of Board members to Board meetings **Comments:**
Other criteria **Comments:**
OVERALL STATEMENT:

Appendix 6

Overview of Documents and Other Information Requested

Nr.	Document	Date of request	How?	Date of receipt	Comment
1.	English version of the Dutch Regulation on the Ctgb and the Decree on the mandate	09/01	Oral, at the Ctgb meeting	30/01	Also available from the Ctgb website
2.	Report internal Ctgb evaluation	29/01	email	16/04	Received
3.	PAPPAS study	29/01	email	29/01	Received
4.	PPT presentations of the first IVC meeting	01/02	oral	04/02	Received
5.	Inventory of and access to all technical, procedural and guidance documents related to the scientific process and that are currently in use.	04/02	email	15/02 21-25/02	Several documents embedded in other documents, embedded in again another document: Handbook Authorization Manuals: EU GD's for Pesticides and Biocides. Evaluation manuals could not be opened. Ctgb Quality Procedures Guide, provided through the EL&I WebTP secured website; accessible for 7 days only.
6.	Inventory of and access to legal documents relevant for the work of the Ctgb.	04/02	email		Not received from Ctgb but compiled by the IVC
7.	Access to documentation about selection and evaluation criteria for scientific staff and management, including staff training policies (initial and continuous training).	04/02	email	21/03	Documents on recruitment, initial training and staff training. All in Dutch
8.	Detailed organisational chart of scientific staff and management (CVs, descriptions of functions and responsibilities, and identification of critical functions).	04/02	email	21/03 16/04 03/05	List of staff, department and functions and descriptions of all functions were provided. Responsibilities and CV's are still lacking A selection of CV's received

Nr.	Document	Date of request	How?	Date of receipt	Comment
				08/05	A revised set of CVs were received + a new set (MB and relevant staff of the Organisation & Innovation department) An Excel spreadsheet was received with a summary of specific CV items
9.	Access to Declarations of Interest (DOI) of all scientific staff and Board over the last 5 years.	04/02	email		
10.	Access to reports/documentation of internal and external scientific peer review processes and evaluations.	04/02	email		
11.	Access to documentation about procedures for formal complaints by dossier owner(s) and interested third parties and records of how these complains have been addressed, including the history (5 years) of formal appeals	04/02	email	18/03 19/03	A list of formal complaints (2011-2012) (could not be accessed) and a list of communications about complaints to the Board. An explanation of the procedure(in English) was attached; Accessible files were provided
12.	Access to written communication with applicants.	04/02	email		Included in dossiers?
13.	Access to documentation of Mutual Agreement (MR) procedures.	04/02	email		
14.	Access to minutes of meetings of the Ctgb Board and of meetings of the scientific staff (both scientific and procedural).	04/02	email	05/03 18/03	provided through the EL&I WebTP secured website; accessible for 7 days only. Clarification of abbreviations received
15.	List of formal Decisions 2012-2011 with dates	04/02	email	11/02	Excel table with hyperlinks to the EU publications of

Nr.	Document	Date of request	How?	Date of receipt	Comment
	of submission, acceptance and adoption			01/03 11-12/03	these approvals Corrected list received Amended table with further details about PPP's and Biocides
16.	List of the most recent 20 DARs (Draft Assessment Reports) of new active substances and reassessments of existing substances	12/02	email	15/02 18-20/02	Email: list of names only Table of 20 DARs with references to the full EU Report
17.	A list of active biocide substances for inclusion in Annex 1 for which the Ctgb has drafted the so-called CARs	27/02	email	27/02	A list of 8 DAR's together with a link to the Commission website for full reports of all active substances
18.	Request for the full dossier including the CAR for Active Substance No 2	27/03	email	08/03 31/05	Dossier received by email and embedded links. Missing parts (MS comment on the human toxicity)
19.	Background documents to the DARs, starting with for active substance No 1	01/03	email	05/03 07/06	Documents for Active Substance No 1 were provided through the EL&I WebTP secured website; accessible for 7 days only. Additional addenda provided
20.	Further background documents to the DARs	02/03		06/03	EFSA references to other DARs were added (most links were not active)
21.	Request for English translation of 12 priority dossiers, starting with PPP Product No 2 and Biocide Product No 2	14/03	email	27/03 10/04	English translations of PPP Product No 2 Biocide product No 2 were received. English translation of Biocide Product No 1 was received
22.	Information about abbreviations of additional functions of Board members	18/03	email	20/03	Received

Nr.	Document	Date of request	How?	Date of receipt	Comment
23.	Request for English translation of PPP Product No 3, Biocide Product No 1, Active Substance No 1 and Active Substance No 2 and relevant reference documents	03/04	Email	10/04 12/04	PPP Product No 3 dossier in English received Biocide Product No 1 dossier received in English
24.	Request for a list of rejected application requests	03/04	email	07/05	Received in three successive emails
25.	Request for English versions of missing documents for PPP Product No2 and Biocide Product No 2	03/04	email	04/04 10/04 05/04	PPP Product No 2 documents received Additional note received on PPP Product No 2, discussed by the Board and on Biocide Product No 2 Biocide Product No 2 documents received
26.	Request for 3 ppt presentations for meeting of 17/04	03/04	email	16/04	Received
27.	Request for the Czech evaluation of PPP Product No 1 (the basis of the Dutch Decision)	11/04	email	14/04	Was sent by Ctgb, but not received by the IVC. Was resent on 21 May
28.	Request for the original CAR for Active Substance No 2, not the draft final of May 2009	12/04	email	13/04 31/05	CAR proposal of 2007 was received Member States comments
29.	The documentation for the original authorization of xxxxxxx as the decision of Biocide Product No 1 is built of this dossier (in English)	14/04	email	15/04	Clarification was provided confirming that the requested info was included in an email sent on 12/04
30.	CVs of Board members and their alternates	23/04	email	26/04	Received
31.	A list of 27 questions the first draft of which was shared with the Ctgb on 17 April	26/04 16/05	Email Renewed	09/05	Responses received on a number of questions but not all

Nr.	Document	Date of request	How?	Date of receipt	Comment
			request		
32.	PAN-Europe report	17/05	email		It was agreed to share this report only after the IVC work was done and the report delivered.
33.	A clarification about the staff not to be considered as part of the scientific staff	23/05	email	28/05	Received as an updated spreadsheet

Appendix 7

Subjects for which Additional Information was Requested together with Written Supporting Evidence

Professional qualifications of internal and external staff

IVC question 1:

What percentage of the internal scientific staff participating in the work of the Ctbg over the period 2010-2013 has:

a. *an university education and what percentage also has a post-graduate education ?*
b. *completed a post-graduate education in toxicology or environmental sciences and what percentage has completed a University education in Chemistry, Biology, Botany, Zoology, Veterinary Medicine, Human Medicine or Natural sciences?*
c. *regularly participated in the work of European or International scientific/ regulatory Organizations competent for pesticides/chemicals safety evaluation ?*
d. *published one, two or three scientific papers on PPPs or biocides in peer reviewed scientific journals?*
e. *been invited to give a presentation in the Netherlands on scientific issues concerning the safety assessment of PPR or biocides?*
f. *been invited to give a presentation in countries other than the Netherland on scientific issues concerning the safety assessment of PPPs or biocides?*
g. *Has participated at least once or twice in training/refresher courses concerning safety assessment of PPPs or biocides?*

The same questions should be applied to the external collaborators of Ctgb for the same period 2010-2013.

Ctgb response to question 1

a) 35% of the staff scientific staff has a PhD, 95% of the scientific staff has an university education.
b) The scientific staff consists of 48 scientific assessors from which 2 have a BSc, 28 have a MSc, 18 have a PhD. All MSc's have completed an University education in the field of Chemistry, Biology, Botany, Zoology, Veterinary Medicine, Human Medicine or Natural sciences. With respect to the expertise field human toxicology, the staff consists of 10 scientific assessors from which 6 registered toxicologists and 4 who study for registered toxicologist with an expected registration in 2013 (2) and 2015 (2). From this group 4 people have a PhD in a related field. With respect to the expertise field 'Environment' the staff consists of 21 scientific assessors of which 8 have a PhD in a related field.
c) 50% of the scientific assessors participates in the work of European or International Organizations relevant for the field pesticides/chemicals safety evaluation. In principle Ctgb participates in every EU Expert meeting (PRAPeR for PPP and TM for biocides).
d) 38% of the scientific assessors has published one, two or three scientific papers on PPPs or biocides in peer reviewed scientific journals.
e) 27% of the scientific assessors has been invited to give a presentation in the Netherlands on scientific issues concerning the safety assessment of PPR or biocides.
f) 34% of the scientific assessors has been invited to give a presentation in countries other than the Netherland on scientific issues concerning the safety assessment of PPPs or biocides.
g) 56% of the scientific assessors has participated at least once or twice in training or refresher courses concerning safety assessment of PPPs or biocides. The education/training of experts depends on the needs of the Ctgb and the basic education level of the assessor. In some cases Ctgb is interested in specialized knowledge. If so, this is already described in the vacancy profile. In other cases assessors are needed for the full spectrum of activities within an aspect. Depending on the need of the Ctgb and the knowledge brought in by the new assessor, an education plan is made. This might be broad (all kinds of applications, biocides and plant

protection products), but might also be focused on special subjects. For this we also use the 'lists of expertises' (takenlijst) to decide which expert would need to develop knowledge on a specific expertise/subject. Depending on the already available knowledge of a new colleague, additional courses/education can be followed. The most 'clear' education plan is the plan for the toxicologists resulting in a European registration as qualified toxicologist, as was presented by the Manager Business Operations.

Professional qualifications of external experts

Granting work to external experts is done for two reasons:

1. the Ctgb does not yet have enough staff capacity to be able to cope with the work load in house. The external expert is set to work at the Ctgb office, his/her work is done under the direct responsibility and supervision of the Ctgb and the Ctgb monitors the quality via peer review by Ctgb staff
2. the Ctgb lacks a certain expertise (higher tier studies). Based on an overview available, the coordinator of the application selects the evaluation institutes with the required expertise and knowledge. After delivery, peer review of the work is carried out by Ctgb staff (nazorg).

We have Service Level Agreements (SLA's) with ten evaluation institutes. In these contracts the minimal level of the qualifications of staff working for the Ctgb has been laid down, in terms of education, experience and work history. For different types of work, different qualifications are required. The evaluation institutes have to show in advance that the relevant demands are being met. Via peer review, carried out by Ctgb staff, of the products and reports delivered by the evaluation institutes, the quality of those products is monitored.

Beginning 2013, the Ctgb requests to evaluation institutes to upload on an structural and regular basis the recent CVs of the staff working for the Ctgb. This in addition to the demands on qualification, confidentiality and integrity agreements which are already in place.

Since Ctgb's own staff has significantly increased during the last year, we expect that the amount of work that is carried out by external experts will decrease. However, external expertise is always needed to ensure flexibility in handling workload and because certain specialities are too small to have it ourselves.

Quality of the scientific process

IVC question 2:

What is the current approach adopted by the Ctgb to keep track of new scientific publications and environmental monitoring data which may be relevant for motivating the reconsideration of already adopted opinions on PPPs and biocides?

CTGB response to question 2:

The Ctgb has appointed specific staff members to monitor a specific field of expertise. These staff members have the responsibility to keep track of new scientific publications on that subject. For every scientific assessor 4 hours per month is reserved to do this and 40 hours per year to participate in workshops, conferences and seminars apart from the time the staff member is representing the Netherlands in international fora. In addition, Ctgb has an 'information specialist' who searches public literature, magazines, news papers, EFSA website, ECHA website etc. and combines the most relevant general information into a news bulletin, which is sent to all Ctgb employees and the Board

with a frequency of once per month. More specific and detailed (scientific) news is forwarded by the information specialist to the relevant expert(s).

Use of monitoring data in the assessment of the fate and behaviour of plant protection products:

Groundwater

In the assessment of the leaching potential to groundwater, monitoring data in groundwater that is available in the DAR is summarized. When available, these data are used to check whether or not these data confirm the concentrations calculated using leaching models (PEARL/GeoPEARL). In addition, when enough information is available, it is checked for each monitoring location whether the 90th percentile concentrations exceed the agreed limit.

Recent data presented in RIVM Rapport 607310001/2007 are used as background information in every assessment. These monitoring data were collected in 2006 in the framework of groundwater monitoring for the Water Framework Directive starting situation (so-called nulmeting) in the Dutch provinces Drenthe, Flevoland, Friesland, Gelderland, Groningen, Noord-Holland, Overijssel, Utrecht and Zeeland. No check was performed on the measurements as is required for use of the data in registration assessment, as this was not included in the project remit. Therefore, the presented values can not be used as such in registration procedures.

In addition to the above mentioned sources of information, the applicant may also submit monitoring data to be used in the registration process. For substances which according to the first tier of the decision tree for leaching to groundwater have a leaching potential, monitoring data in the upper groundwater (0 and 1 metre below the groundwater table) can be used in the second tier. Finally, in the third tier the applicant can demonstrate by means of monitoring that the concentration in the groundwater at 10 m depth remains below the agreed limit. The procedure and the interpretation of monitoring is described in more detail in the following report:
A.A. Cornelese, J.J.T.I. Boesten, M. Leistra, A.M.A van der Linden, J.B.H.J Linders, J.W. Pol, A.J Verschoor, Monitoring data in pesticide registration., RIVM report 601450015/2003, RIVM, 2003
http://www.rivm.nl/bibliotheek/rapporten/601450015.pdf

Surface water

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used in the surface water assessment to evaluate measured concentrations of plant protection products and biocides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values (authorisation threshold, Maximum Permissible Concentration). The Pesticide Atlas contains recent monitoring data (1997-2011) from Dutch Waterboards. When concentrations of PPP's are observed exceeding the limits and this is significantly correlated to an already authorised use, for which the applicant also seeks registration for his product, then the applicant is required to submit an adequate risk assessment in which it must be shown that the observed exceeding of the limit is not caused by the PPP applied for.

For examination against the drinking water criterion, another database (VEWIN (drinking water board)) is used containing recent monitoring data at surface water abstraction points destined for the production of drinking water. For new active substances (less than 3 years authorisation), a preregistration calculation is performed to calculate the concentration at drinking water abstraction points. For existing substances (authorised for more than 3 years) for which a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

IVC question 3:
What is the current approach to verify that the decisions adopted by the Ctgb on PPPs and biocides

do not result in unpredicted and undesirable environmental effects in the Netherlands ? Is there an effective system in place for ensuring that Ctgb is informed of relevant results and to ensure reactivity to data coming from "regular" uses of the products authorized?

Ctgb response to question 3:

There is an effective system for monitoring of ground and surface water (see also the answer to question no. 2. For questions/incidents related to human poisoning professionals in healthcare contact The National Centre for Poisoning Information (https://www.vergiftigingen.info/home.htm). The Ctgb analyses the annual report of the National Centre. With regards to residues: in the Netherlands and in EU, programs are established yearly for the monitoring of pesticide residues in food. Results are reported in annual reports; in the Netherlands by the NVWA (Netherlands Food and Consumer Product Safety Authority) and in Europe by the EFSA. Based on the Dutch report, Ctgb checks whether MRLs (maximum residue levels) in Dutch products were exceeded, after publication of the report. Connections between Ctgb and NVWA are very close, with frequent meetings (at least four times a year) and e-mail communication. In case regularly occurring exceeded MRLs appear to arise from an authorisation of a PPP, NVWA will alert Ctgb. In that case, Ctgb can take the necessary actions to amend or revoke the authorisation.

IVC question 4:

Does Ctgb has in place any systematic procedure to evaluate, through an in-dependent approach, the quality of the scientific process especially with regard to:

a. the full understanding by the internal/ external scientific staff of and their compliance with the different risk assessment methodologies being used by Ctgb?
b. the coherence, clarity and comprehensibility of the scientific opinions provided to the Management Board of Ctgb? Is the basis for the decision (motivation) clearly spelled out ?
c. Inclusion of specific scientific knowledge about agriculture and environment in the Netherlands (e.g. microbiological resistance prevalence, efficacy)

Ctgb response to question 4:

Ctgb has currently no formal procedure in place to systematically evaluate the intrinsic scientific quality of its products. On ad hoc basis we do evaluate the scientific output on consistency, clarity etc.
Basically, the Ctgb has organized a system at the front side of the process ensuring the scientific quality by identification of roles with responsibilities, evaluation manuals, peer reviews (inter-colleagual checks) and communication. The initiative of the Ctgb to invite international independent experts to evaluate the scientific quality of Ctgb outputs is a first step to a systematic procedure to monitor and evaluate the quality of the scientific products and the scientific process and learn on a structural basis.
We do have ISO certification which focuses on the process and procedures for intake, assessment and decisions. Moreover, we do have an internal peer review process and the Board, consisting of specialists in their fields does a last and thorough review of the scientific assessment. So quality control is present, though there is no formal monitoring system in place.

IVC question 5:

Level of work pressure on Ctgb scientific staff resulting from excessive workload and time pressure during the period 2010-2012. (e.g. deadlines not met; extension of the deadlines, etc.). Are there any indicators to track this (e.g. staff turn-over, level of staff motivation)?

Ctgb response to question 5:

Results from the "Personnel Monitor" and data on sick leave are considered indicators of work pressure. During the last few years, the work pressure has been high, as shown by the "Personnel monitor" data of December 2011, especially in the expert teams Environment and Efficacy. This was one of the reasons to significantly increase the Ctgb staff which has resulted in a steep drop in sick leave over the last two years (from more than 8% to 3%).
The level of work pressure has not affected the level of satisfaction with the offered (scientific/career) development opportunities the Ctgb offers its staff.

The observation that Ctgb was not able to comply with deadlines is an indicator for a high workload, but as such not an indicator for time pressure and work pressure on the scientific staff. Not all deadlines have been met over the last few years. This is due to:

a) The fact that the number of applications cannot be controlled (we are legally obliged to accept every application);
b) changes in legal landscape: PPP and biocides act, regulation of PPPs and upcoming implementation of biocides regulation;
c) design of new processes to improve efficiency; and
d) supervision of new staff

Measures that have been taken to reduce the amount of applications for which deadlines are not met, include attracting new staff, prioritizing the work very strictly, implementing the efficiency measures. Priorities in work for the first half year of 2013 have been set by the management team on January 29th and adopted by the Board in its February meeting. For PPPs priority is given to products in these product types:

1. European substances
2. Reregistration
3. Zonal applications
4. Helpdesk-questions speciality crops
5. Applications speciality crops
6. "Leftovers", prioiritized by applicants

For biocides, priority is given to products in these product types:

1. Biocides in the "differentiated enforcement group"
2. "New" European substances
3. "Old" European substances
4. Applications as RMS
5. Applications as CMS
6. Applications for which the applicant has prioritized the biocide

Other products will be worked on only when capacity is sufficient.

IVC question 6:

Does a formal procedure exist for extending the legal deadlines which cannot be met and for analyzing the reasons for delays? Are there any time-frame suspension mechanisms and on which grounds can they be instigated?

Ctgb response to question 6:

There is a formal procedure regarding the renewal of authorizations for specific active substances,. Commission Regulation (EU) No 1141/2010 lays down the procedure for the renewal of the active substances in Annex I to 91/414/EEC. Applications are made under Directive 91/414/EEC, but decisions on approval will be taken under Regulation (EC) No 1107/2009, including the criteria laid down in Annex II to the Regulation. Guidance to supplement the renewal Regulation has been

published on the Commission's website.
(http://ec.europa.eu/food/plant/pesticides/approval_active_substances/procedures_renewal_en.htm)
Recently, the Board has adopted a proposal of the secretariat for criteria to be met for an extension of the legal deadline. Two criteria must be met: (i) the delay is not caused by the applicant; and (ii) no new risks are foreseen for the application influencing the possible approval of he renewal.

IVC question 7:

Are the Members of the Ctgb internal and external scientific staff requested to sign annual and subject specific declarations concerning possible conflicts of interests? If so, are these declarations publicly accessible? Are there any review mechanisms of such declarations? Who and when decides on whether a conflict exists or not ?

Ctgb response to question 7:

Declarations of interest are routinely requested from external staff (from the employee in person and from the employer). Ctgb can provide the IVC access to this documentation, e.g. during the visit of 11, 12 June 2013. Decision whether a conflict of interest exist is the responsibility of the Ctgb. Integrity is on the agenda of the meetings of Ctgb with employers of external staff, that occur twice a year. Review of issues is discussed here. Internal staff swears or affirms at the start of their contracts to behave as a dutiful civil servant, confirmed in a written document. In addition, employees have the obligation to immediately report any potential conflict of interest. Recently Ctgb put in place a procedure to sign annually the declaration of interest. The first time a request for DoI's distributed organization-wide was 3 May 2013. Results, once compiled, are accessible for the IVC. Ctgb can provide the IVC access to this documentation, e.g. during the visit of 11, 12 June 2013.

***IVC question 8**:*

What are the determining elements in deciding whether external experts are to be involved in a specific evaluation? Who decides such involvement and is this a formalized procedure, i.e . a motivated decision? Could a dossier in practice be dealt with fully by external evaluators (apart from the general planning coordinator's role)?

Ctgb response to question 8:

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In general, when expert knowledge is not sufficiently available at Ctgb, external experts are involved e.g. for several higher tier studies for fate and behaviour and for ecotoxicology and for studies for efficacy. The number of studies for which Ctgb has not full up to date expertise available is limited and is mainly apparent in specific higher tier environmental options. An overview of expertise fields where Ctgb knowledge is not sufficient and external experts are involved is listed in the document 'knowledge internal/external. Ctgb experts are assigned to keep up with the developments in their field of expertise (list of special expertises). These Ctgb experts are involved in preparing manuals for summarizing and evaluating these complex studies. Examples are mesocosm studies, earthworm field studies and field studies with non target arthropods. These experts are capable of asking the relevant questions during the peer review and to make sure that the quality is secured.

For biocides and human toxicology, in the EU methods for exposure estimates are developed per Product Type and for many applications there is still no agreed method. In the Netherlands RIVM has a lot of knowledge in this area and we use that expertise e.g. for writing CARs. The check is done by Ctgb experts by review. When relevant Ctgb experts will follow a course at RIVM. E.g. in June Ctgb toxicologists will follow a course at RIVM on the model ConsExpo. From there Ctgb will decide what the next step will be to extend our knowledge in this area.

Another reason to involve external experts is the need for additional capacity. This can be decided by the planning coordinator. For national product authorizations outsourcing of a complete dossier is in theory possible, but is avoided whenever possible. It was not needed in the past 5 years. For active substances (writing a DAR or CAR), a dossier can be fully dealt with externally. But subsequently the DAR or CAR will be critically peer reviewed by Ctgb and amended where needed before the document is sent to Europe for comments from other member states.

All evaluations for national product authorisations are peer reviewed by a Ctgb employee. This refers also to evaluations prepared by external experts in a process step called 'nazorg'. This peer review ensures that external experts work in a manner coherent with risk assessment framework adopted by Ctgb. The task for peer review of evaluations regarding highly complex higher tier studies is distributed following the list of special expertises (takenlijst), which allocates the fields of expert knowledge of Ctgb risk assessors.

***IVC question 9**:*

With regard to the peer review process for evaluations conducted:

a. *Are all evaluations conducted by Ctbg or by external staff subjected to peer review? If not what criteria are used to select evaluations to be subjected to peer review?*
b. *For each peer review to be conducted is one individual secondary reviewer deployed or are evaluations completed subjected to peer review by all evaluators working in the sector concerned?*
c. *Where relevant, what criteria are applied in selecting /identifying a secondary reviewer for evaluations conducted by Ctbg evaluators?*
d. *Where relevant, what criteria are applied in selecting /identifying a secondary reviewer for evaluation conducted by scientists from external agencies?*
e. *What approach is taken in conducting peer reviews: is a detailed check of the evaluation of individual studies conducted, or is the focus on particular groups of studies, endpoints or issues. Please respond with examples from each of the disciplines (toxicology, fate and behavior, environmental toxicology, definition of the residue etc)*
f. *How are peer reviews documented? Please provide the peer review documentation generated in the consideration of the five authorization decisions and the DAR and CAR selected for detailed examination by the IVC (English translations are required if the documentation is not already in English).*

Ctgb response to question 9:

a) Yes, all evaluations for national product authorisations are peer reviewed by a Ctgb employee and this is explicitly clear in the documentation, because the peer review is part of the template ("collegiale toets"). The risk assessment is a product compiled of contribution of various scientific assessors, in which the following expertise fields are represented: physical chemistry and analytical methods; human toxicology, residues, environment fate, environment ecotox and efficacy. Scientific assessors are responsible for the outcome of the risk assessment, and they only. Coordination of the tasks of the scientific assessors (1 for each expertise field) is assigned to the coordinator of the application. The tasks of the scientific assessors concerns 1) a check on the completeness of the scientific dossier and subsequently 2) the risk assessment. Both steps are peer reviewed by a colleague from the same expertise field. There is no joint consideration of the overall outcome by all scientific staff who have participated and provided specific contributions. Consistency between risk assessment for different expertise fields is covered by bilateral contact between risk assessors during preparation of the risk assessment. The tasks of the coordinator of the application concerns. scheduling the tasks for scientific assessors, hiring of external capacity or expertise (following the requirements defined by scientific staff), communication to applicants

regarding (in)completeness of dossiers and progress in the application process, and as a more or less final step compiling the scientific risk assessments prepared for the various expertise fields (protection goals) into one risk assessment that is provided to the board. Also the output of the coordinator of the application is peer reviewed, in this respect with regard to administrative completeness and consistency and compliance with procedural demands. When Ctgb is RMS, contributions of Ctgb employees to the DAR or CAR are usually checked by a colleague. This check, however, is not as of yet part of the quality management system, so it is at the moment not carried out systematically. In addition, it is not yet part of the template and therefore not visible in the documentation. After receiving comments from other member states, the comments are answered. This is in most cases not peer reviewed by a colleague. Difficult questions are however bilaterally discussed with a colleague, but also not documented. In the NRMS process Ctgb decided that no colleagual check per definition will take place. Difficult issues are however bilaterally discussed with a colleague. The result of the Ctgb input is documented in the chronologically comment tables.

b) The peer review is normally conducted by one individual secondary reviewer from the same expertise field, selected according to the lists of special expertises (takenlijst). If needed for a complex dossier an additional experts can be involved but the responsibility lies with the secondary reviewer. Non standard approaches in the risk assessment are subject for discussion in internal expert meetings and may be laid down in standard operation procedures for consistency (job aids).
c) See above. As the expertise groups are still relatively small and colleagues consult each other on a regular basis on their expert knowledge, the scientific assessors are very well able to select/identify the most relevant secondary reviewer.
d) The peer review is normally conducted by a secondary reviewer according to the lists of special expertises. If needed for complex dossier an additional experts can be involved but the responsibility lies with the secondary reviewer.
e) Detail in conduct of peer review depends on type of study. Relatively simple studies will get less attention in a peer review compared to more complex and higher tier studies. For human toxicology e.g. relatively simple oral toxicity studies will be checked superficially, where as exposure studies will be checked individually and in detail. Other factors influencing the detail of the peer review are the degree in which the outcome of the risk evaluation is affected by this specific endpoint and triggers like a relatively inexperienced author of the peer reviewed evaluation.
f) Regarding risk assessments for national authorisations, the first page of the template for the risk assessment contains a collegial check form. This form is filled in after processing of the comments of the collegial check and gives proof that the risk assessment was subject to peer review. However this form gives no or very limited information on the content of the scientific discussion and/or scientific opinion forming. Regarding risk assessments for EU active substance evaluations, no collegial check forms are included in the templates to document peer review. For documents that have been produced within the context of the document management system (DMS), information on the content of the scientific discussion is available in the different versions of the document stored in DMS, but requires comparison of versions and track changes.

IVC question 10:

What are the criteria for staff performance? Are there instruments for rewarding staff (promotion? career advancement? And for underperformers?

Ctgb response to question 10:

- Criteria for staff performance arise from their job description
- Staff has on a regular basis meetings with their team managers. Part of this meetings sequence is

a yearly assessment of their performance. If this is adequate, their salary is increased by a set amount (one scale up the ladder) until the maximum of their specific salary ladder is reached.
- Salaries are conform the national regulation for civil servants (BBRA)
- Extraordinary performance can be rewarded with an extra step up the ladder or a one-time reward.
- Underperformance is dealt with by the team managers, specific measures can be taken by them to improve performance. Permanent underperformance can lead to termination of the contract.
- Career opportunities within Ctgb are limited.

IVC question 11:

Why are negative Ctgb Board Decisions not published?

Ctgb response to question 11:

First, negative decisions of the Board regarding an application are published. However, in many cases a negative decision regarding an application is prevented by partial of complete withdrawal by the applicant. After completion of the assessment the draft risk assessment is sent to the applicant. It is common that the applicant after examination of the outcome of the risk assessment takes the opportunity to withdraw the intended uses that cause an unacceptable risk. Consequently, on a yearly basis, only a limited number of rejected applications is published.

IVC question 12:

Is the Ctgb Board entitled to recommend or require changes in the scientific evaluation report before its publication?

Ctgb response to question 12:

The Ctgb Board is entitled to recommend or require changes in the scientific evaluation report. The Board is responsible for the decision as well as for the legal and scientific basis of this decision. The Board functions within the legal framework, European as well as national but has a limited task, the assessment and authorization of PPP's and Biocide-products. Guidance is either provided for by the EFSA/EC or laid down by the ministries. The secretariat functions completely as a service to the Board but does not have any responsibility on its own. Therefore, the deliberations of the Board concerning the scientific basis of its decisions are part of the internal process and are not open to the public. The end result however is published including the scientific assessment.

Transparency and independence of the decision making process of Ctgb

IVC question 13:

Which entity or body is the Ctgb Board accountable to ? What is the nature, frequency and outcome of controls exercised in this context ?

Ctgb response to question 13:

Ctgb is accountable to the Ministries of Economic Affairs (plant protection products), of Infrastructure and the Environment (biocides, environment, surface water), of Social Affairs and Employment (working conditions), of Health, Welfare and Sport (health). The relation is described in the 'Sturings'

arrangement (governance agreement), that was renewed, recently. Ctgb has the responsibility to draw . every 5 years a multi annual strategic vision, and yearly a work plan including budgets. The Ctgb has to report on a quarterly basis to the ministries.. Twice a year, a meeting is scheduled between the ministries and Ctgb to discuss the work plan and budget (autumn) and annual report and annual account (spring). Every 5 years an evaluation on the functioning of the Ctgb is performed by an external party. The last time this was performed in 2010 by PriceWaterhouseCoopers. Part of this evaluation is interviews with stakeholders in the Ctgb surroundings.

IVC question 14:

Does the Ctgb Board have in place a quality management policy and system ? Is there an internal control system and a risk assessment policy and system (in management terms) in place ?

Ctgb response to question 14:

The Ctgb organisation has a quality management system, ISO 9001:2008, certified by Certiked. This includes also the processes the Board concerning.

IVC question 15:

Has the Management Board of Ctgb adopted an internal procedure to be complied with when dealing with the phase of the authorization procedure under their competence?

Ctgb response to question 15:

The Board is responsible for the complete process from intake to final decision. This process is laid down in the quality management manual, including the process leading to the final decision. In the formal Governance regulation (bestuursreglement) the decision making process is laid down. In general the Board seeks consensus, and doubts concerning specific elements of the draft-advice are communicated with the secretariat and, depending of the importance, either addressed in the minutes (as a note from the secretariat) or lead to a new version of the advice, to be discussed in one of the next meetings.

IVC question 16:

Does a clear separation exist between the draft opinion provided by the scientific staff of Ctgb and the final decision adopted in terms of authorization by the management Board ? If so , is there a clear reference to the scientific opinion provided by the Ctgb scientific staff in the PPPs and Biocides authorization documents adopted by the Management Board?

a) Could Board members give an indication of how much time they generally invest in reviewing the scientific opinions and proposals produced by the scientific staff of Ctgb in preparation of his/her standpoint in the final decision making?
b) Is it possible for external parties to access the scientific opinions and proposals offered by the Secretariat to the Board and the requests and/or comments made by the Board, if any, in addition to the publication of the final decisions of the Board?
c) Do Board decisions exist that are different from the draft decisiom as suggested by the scientific staff? If so, are these registered as such and made public?

Ctgb response to question 16:

This depends on the fact whether the Board accepts the first draft of the advice as base for its decision. If not, the scientific assessment is either clarified or rewritten if a different decision is reached. In the dossier this can be followed in the minutes of the Board meetings and with the help of the version

management of the documents.

a) Time invested

Chair of the Board: The Chair of the Board presides and leads decision making process within the Board and is in the preparation of the decision on behalf of the Board the contact person for the secretariat. The secretariat in general is represented by the director or deputy director. Aside from the relation between Board and secretariat, the chair is engaged in maintaining relationships with the stakeholders, such as applicants, departments, sister organizations, the scientific community, NGO's and the users / consumers. For all these activities, including the preparation of the lecture meetings, the chair spends two days a week. The vice-chair spends 1,5 days a week on this work.
Members of the Board: For each board meeting at least half a day is invested in preparation, depending on the type and numbers of documents, sometimes increasing to 1,5 day. Further there is a regular stream of individual documents send in between the Board meetings that need 0.5-1 hr per document.
Deputy members of the Board: For each Board meeting at least 1,5 day is invested in preparation, depending on the type and numbers of documents, sometimes increasing to 2 days. Further there is a regular stream of individual documents send in between the Board meetings that need 1-1,5 hr per document.

b) The deliberations of the Board nor the changes in the draft decision are published, only the final decision as adopted by the Board is published.

c) Yes, some Board decisions differ from the advice of the secretariat. These differences are noted in the minutes of the Board but not published

IVC question 17:

Please provide copies of the documentation compiled during the consideration by the Board of the five authorization decisions and the DAR and CAR selected for detailed examination by the IVC (English translations are required if the documentation is not already in English).

Ctgb response to question 17:

Documentation compiled for the Board regarding the five authorization decisions already have been provided to the IVC. Up till now, a CAR or DAR was sent to the EU without review by the Board. With the implementation of new procedures for biocides related to the Biocide Product Regulation (528/2012), a CAR delivered by the secretariat will be subject to review by the Board. On a longer term, the Board also will be consulted before delivery of a DAR.

IVC question 18:

Are there Ctgb staff members specializing in legal and specific administrative tasks who are involved in the authorization process of PPPs and biocides? If so, when and to what extent are they consulted?

Ctgb response to question 18:

There are staff members specialized in legal tasks, i.e. legal advisors. The legal advisors are consulted on ad-hoc basis by coordinators of applications or scientific assessors for various reasons, like e.g. letters of access and data protection or explanation of legislation with regard to the mandatory authorization procedure. There are staff members specialized in specific administrative tasks, i.e. Coordinator biocide and PPP applications A. Coordinators A are involved in preparation of

authorizations of parallel imports, derived applications, change of product names etc.

IVC question 19:

In case the Management Board is not satisfied with a specific scientific evaluation on a given product and additional technical and scientific work is required, would that formally be noted in the minutes of the specific procedure or would the request remain verbal?

Ctgb response to question 19:

It will be noted in the minutes of the Board.

IVC question 20:

What are the powers of the competent Dutch Ministry in relation to the decisions adopted by the Ctgb Management Board?

a. What happened when the Ministry of Agriculture ordered "Ctgb to modify a previously taken decision" (Source PAPPAS report page 52); has the legal status of this intervention been validated?

b. Is the Ctgb routinely represented in the Netherlands delegation at the SCFCAH? Has this person decision-making authority on behalf of Ctgb?

Ctgb response to question 20:

In its decision making, the Board is completely independent. Only when the Minister has indications of gross negligence of the legal tasks, the minister can take measures. However, this has never been the case. Reference can be made to the "Kaderwet Zelfstandige Bestuursorganen" (Framework Act Autonomous Administrative Bodies), article 23 (translation).

- If in the judgement of our Minister an Autonomous administrative body seriously neglects its tasks, our Minister can take the necessary measures.
- Except in urgent cases, the measures will not been taken sooner than the Autonomous administrative body being given the opportunity to perform its tasks to a satisfactory level within a period of time determined by our Minister.
- Our Minister informs both chambers of the States-General (the upper and lower houses of parliament) immediately of the measures taken by him within the meaning of the first paragraph.

Response 20a:
It is correct that in 2011, Ctgb performed a re-evaluation of a number of neonicotinoId products (mainly plant protection products). In fact, Ctgb followed the political discussion and – realizing that bee colony collapse constitutes a severe threat, and having taken into account the motion from parliament (motion Ouwehand d.d. 17-2-2011) which asked for a re-evaluation – Ctgb started the re-evaluation before even beiing requested to do so by the junior minister. This is not a matter of Ctgb not being independent, but Ctgb anticipating on scientific and political developments. Based upon a preliminary report by Ctgb, junior minister Bleker mentioned in parliament that he ordered Ctgb to withdraw three plant protection products, containing imidacloprid as an active substance. Ctgb did not await his formal "order", but responded by letter dated April 19 2011. It stated that Ctgb had discussed the outcome of its preliminary report with authorisation holders, and that they agreed to modify their authorisations with mitigating measures which would – given the legally applicable scientific framework – ensure a safe use. By letter of April 22 2011, mr. Bleker asked for clarification, which was given by Ctgb on April 26, 2011. In reaction, on April 28, mr. Bleker asked Ctgb to withdraw three spraying applications. By letter of May 13, 2011, Ctgb refused, as there was not enough scientific evidence to substantiate the requested withdrawal, elaborately explaining that Ctgb could not meet the burden of proof. On June 1, 2011, junior minister Bleker suspended the spraying applications

untill Ctgb had finished the re-evaluation. This was based on the "Kaderwet Zelfstandige Bestuursorganen" (Framework Act on Autonomous administrative bodies, which allows him to undo annul the decisions (in this case: the authorisations) of Ctgb. With his Decision of July 14, 2011, the Secretary of State cancelled the annulment.

Response 20b:
Due to European law Member States are represented by their Ministry during the SCFCAH-Legislation meeting. The SCFCAH plays a pivotal role in the EU approval of active substances for plant protection products. The Ctgb is not responsible for the authorization of active substances, but has an advisory role towards the minister.As a competent authority, the Ctgb advises the Ministry before and during the meeting. The Ctgb is therefore in person represented during the meeting, but has no right to vote. The delegate of the Dutch Ministry of economic affairs has the authority to vote for the Netherlands.

IVC question 21:

Do procedures exist to make possible an internal or external redress or appeal by the applicant against a decision of Ctgb on a specific product? If so, how many such cases have been lodged during the period 2010-2013? Could statistics be provided on number of redress/appeals lodged and the outcome? How many have been subject to further judicial review and what has been the outcome (cases won, lost, dropped)?

Ctgb response to question 21:

The Dutch law provides an objection and appeal procedure. Regarding the objections and appeals that have been presented during the triennium 2010-2012 the following data are available.

Year	Object-ions	Well-founded objections	Pending objections
2010	24	8	0
2011	35	5	11
2012	54	11	17

Appeals	Appeals to court	Well-founded appeals	Pending appeals
0	0	0	0
3	3	3	3
3	2 (1 appeal withdrawn)	0	2

An analysis, that interprets the above mentioned data on objections and appeals, is yet not available. In 2012 two appeals went to court. Earlier, information on the objection procedure has been sent March 18, 2013 11:21 AM.

IVC question 22:

What is the procedure for appointing the members and the chairman of the Ctgb Management Board?

Ctgb response to question 22:

Essentially, the Board defines the profile to fulfil the vacancy searching a balance between the available and the required expertises in the Board. The minister is in charge for recruitment, selection and appointment.

IVC question 23:

Is the Chairman of the Ctgb Management Board elected by the Members of the Board or appointed by the competent Governmental Authority?

Ctgb response to question 23:

The Chairman is appointed by the minister of economic affairs with consent of the minister of Infrastructure and Environment).

IVC question 24:

Can any member of the Ctgb Management Board be dismissed before the mandate expires? If so, under which conditions?

Ctgb response to question 24:

Dismissal of a member of the Ctgb Management Board is legally possible, but only by the minister. Reasons for dismissal can be e.g. a request of a member of the Board based on personal reasons, or when the member is proven to be incompetent for the job. Reference can be made to the "Kaderwet Zelfstandige Bestuursorganen" (Framework Act Autonomous Administrative Bodies, articles 12 & 13 (translation).
Article 12 of the Framework Act Autonomous Administrative bodies says:

- Our Minister appoints, suspends and dismisses the members of an Autonomous administrative body.
- Suspension and dismissal take place only in cases of unsuitability for or incompetence in the role being performed and/or due to other important reasons relating to the character of the person concerned. Employment may also be terminated at the request of the person concerned himself/herself.

Article 13 of the Framework Act Autonomous Administrative bodies says:

- A member of an Autonomous administrative body fulfils no additional roles that would be undesirable with an eye to the good performance of his/her role or the preservation of his/her independence or confidence in such independence.
- A member of an Autonomous administrative body reports to our Minister any intention to accept an additional role other than roles arising from his/her role.
- Additional roles of a member of an Autonomous administrative body other than those arising from his/her role will be made publicly known. Such public disclosure takes place through making a statement of these additional roles available for inspection, with copies held by the Autonomous administrative body and our Minister.

IVC question 25:

Are the Members of the Ctgb Management Board requested to sign general and specific declarations concerning possible conflicts of interests? If so, is there any review mechanisms for such declarations? Are these declarations accessible to third Parties?

Ctgb response to question 25:

It is a legal obligation for each member of the Board to report it's interests (secondary employment, additional activities, etc) to the Minister (article 13, paragraph 2, "Kaderwet Zelfstandige Bestuursorganen" (Kaderwet ZBO). All Members the Board have signed the general and specific declarations concerning possible conflicts of interests. The declarations of interest are accessible to third Parties on the Ctgb website:
http://www.ctb.agro.nl/portal/page?_pageid=33,32926&_dad=portal&_schema=PORTAL .

IVC question 26:

Are members of the Management Board and of the internal and external staff of Ctgb liable for

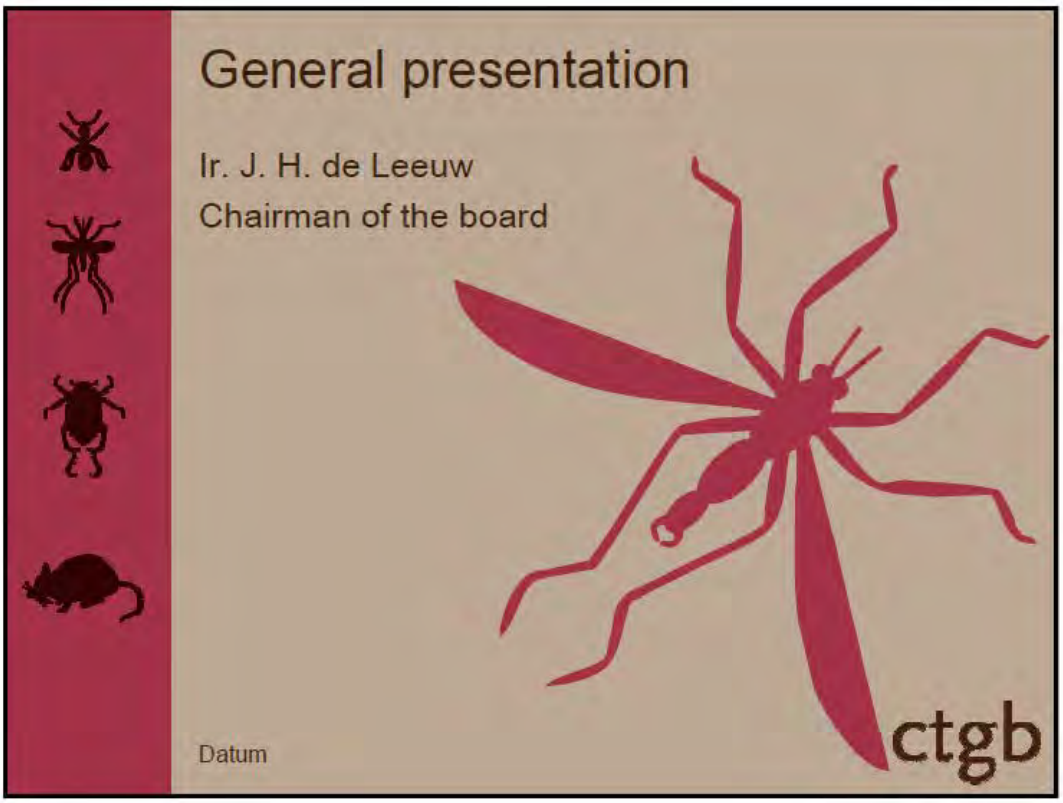
possible damages associated with decisions adopted on specific PPOPs or biocides?
Ctgb response to question 26: In normal cases, members of the Management Board and of the internal and external staff of Ctgb are not liable for possible damages associated with decisions adopted on specific PPPs or biocides. Only in extreme cases of verifiable criminal behaviour, members of the Management Board can be liable.
IVC question 27: *Are the Members of Ctgb Management Board also in charge of staff policy including recruitment, salary and other compensations and career development options?*
Ctgb response to question 27: Members of the Board are not in charge of staff policy like recruitment, salary and other compensations and career development options. In general, the Ctgb follows the rules for salary, labor conditions etc of the Dutch government. Members of the Board however give consent to the appointment of the director/secretary and deputy director/secretary and authorize the strategic plan, work plan, budget and quarterly and annual report.

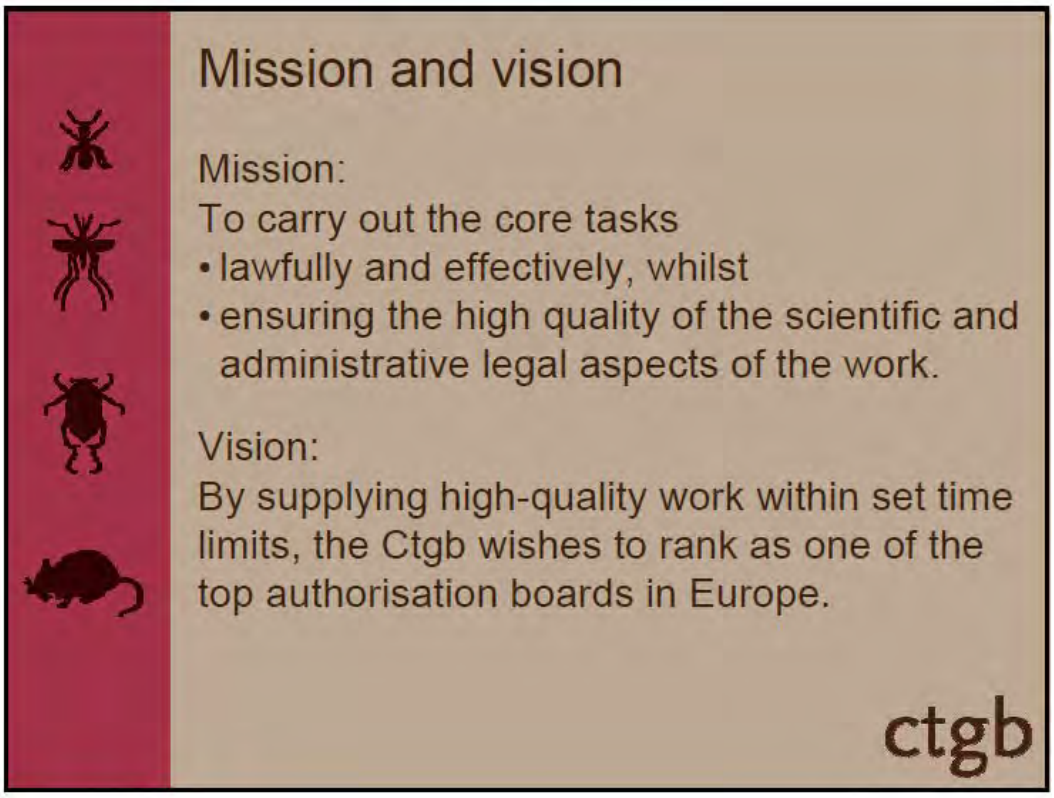
Appendix 8

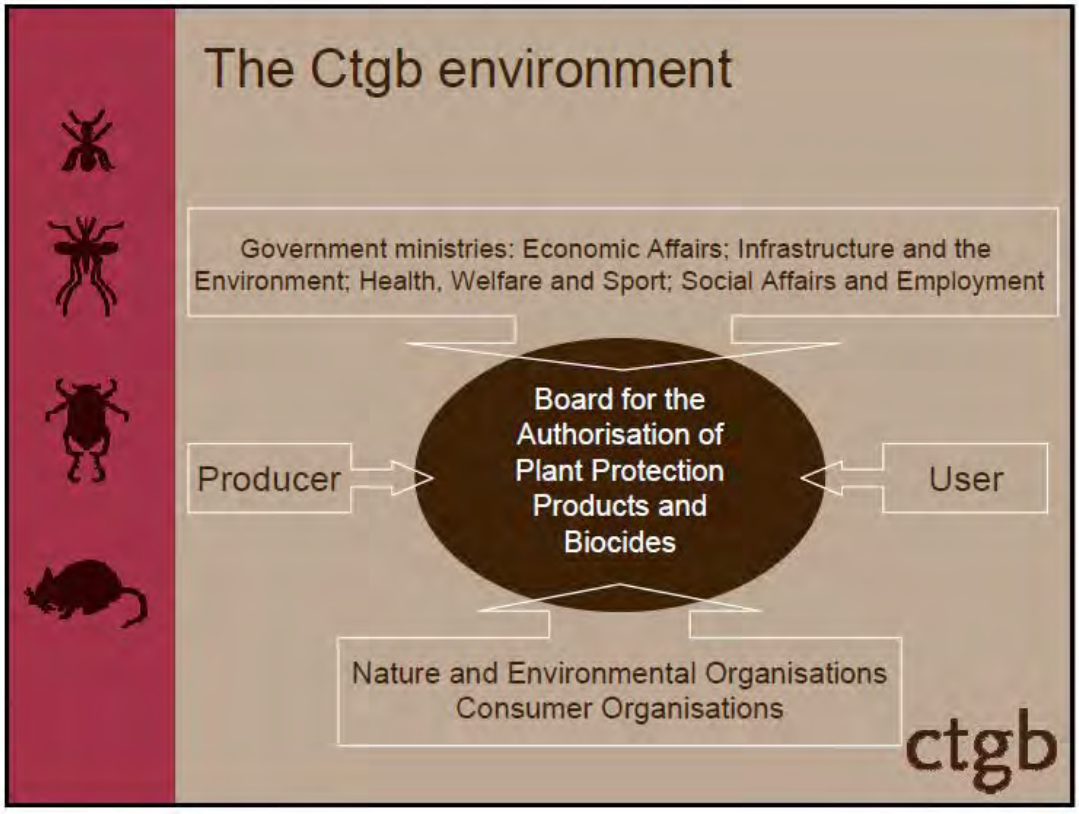
Presentations made by the Chairman, the Director and Senior Staff

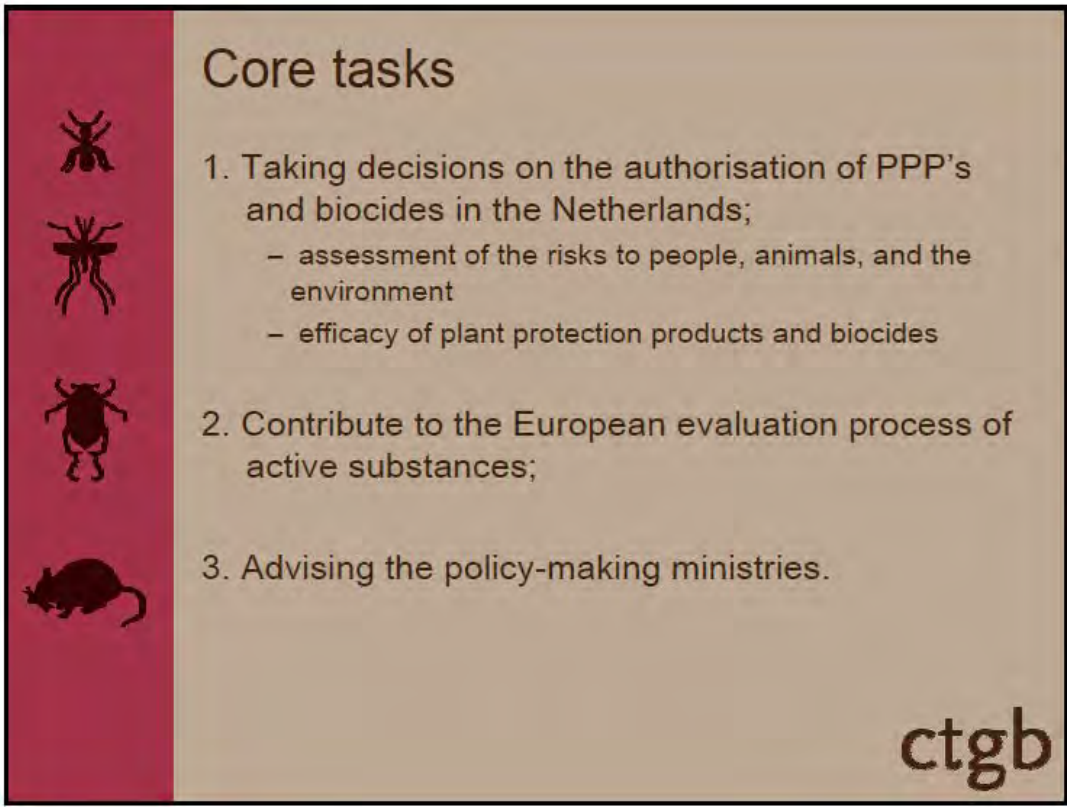
Appendix 8: Presentations made by the Chairman, the Director and Senior Staff (Continued)

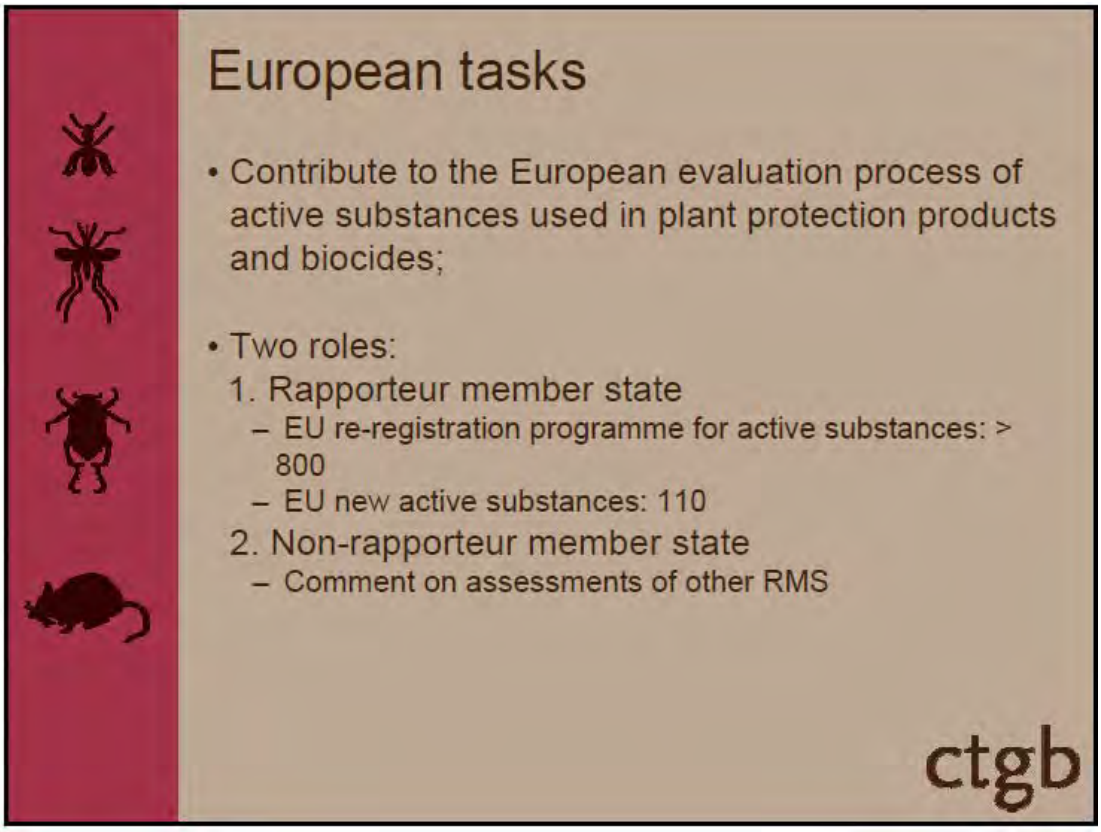
1 Presentation of Ir JH de Leeuw, Chairman of the Board

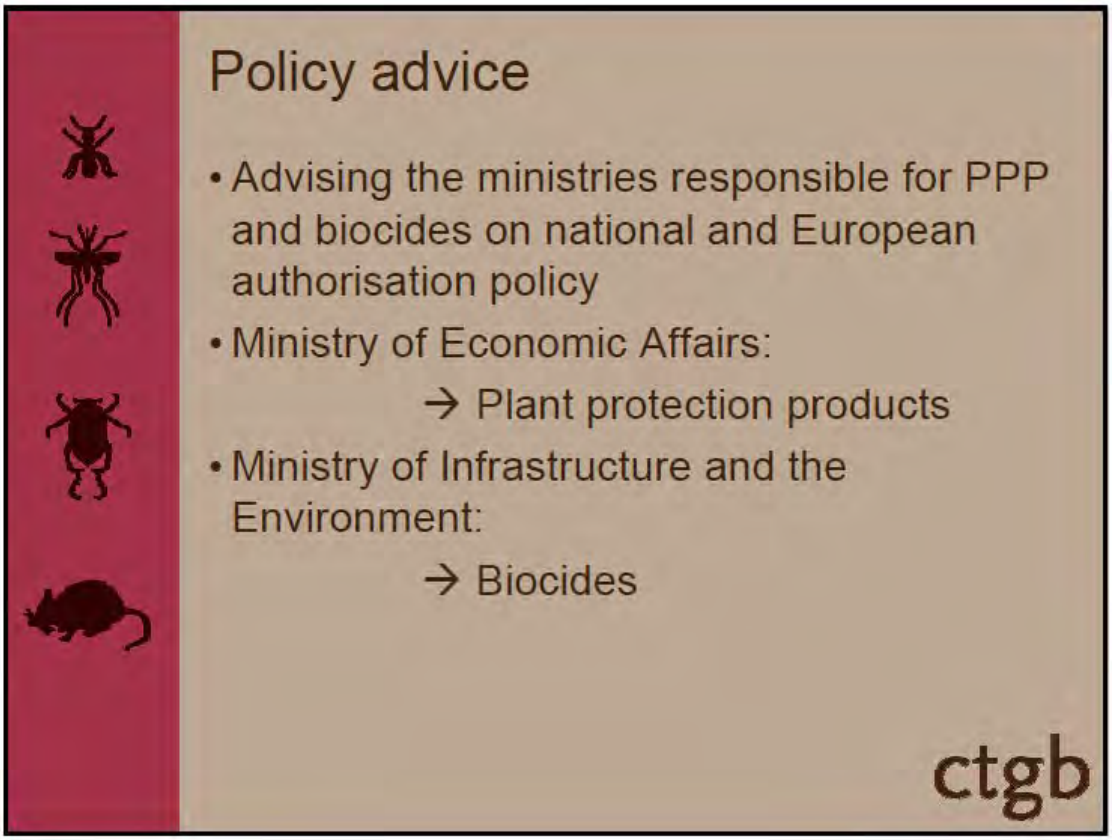


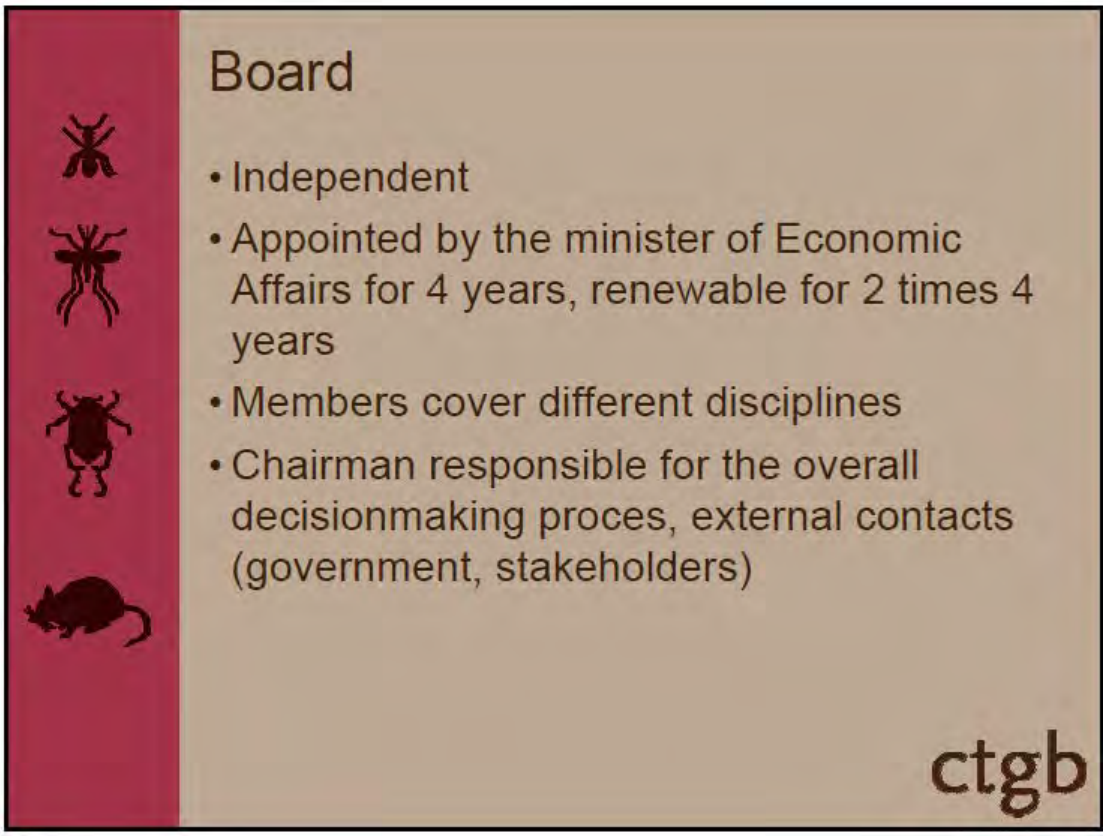


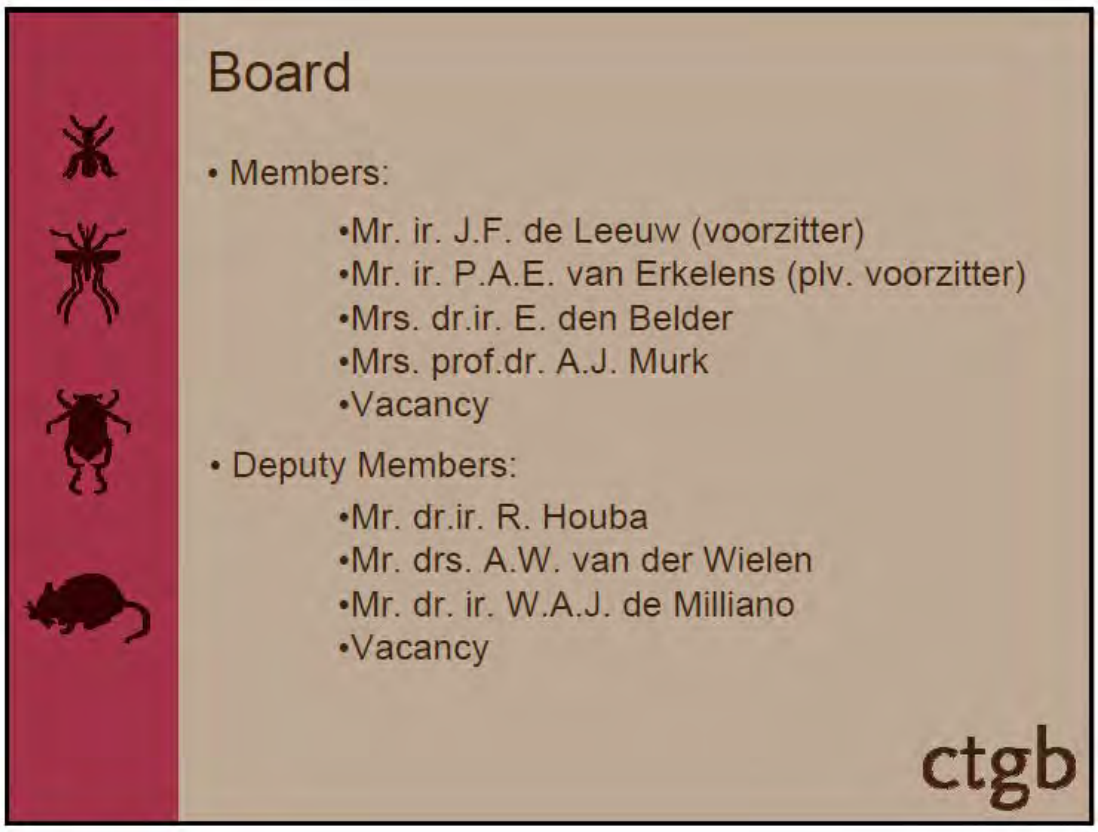

The Ctgb environment
Government ministries: Economic Affairs; Infrastructure and the Environment; Health, Welfare and Sport; Social Affairs and Employment
Board for the Authorisation of Plant Protection Products and Biocides
Producer
User
Nature and Environmental Organisations
Consumer Organisations
ctgb


Core tasks
1. Taking decisions on the authorisation of PPP's and biocides in the Netherlands;
– assessment of the risks to people, animals, and the environment
– efficacy of plant protection products and biocides
2. Contribute to the European evaluation process of active substances;
3. Advising the policy-making ministries.
ctgb


European tasks
• Contribute to the European evaluation process of active substances used in plant protection products and biocides;
• Two roles:
1. Rapporteur member state
– EU re-registration programme for active substances: > 800
– EU new active substances: 110
2. Non-rapporteur member state
– Comment on assessments of other RMS
ctgb

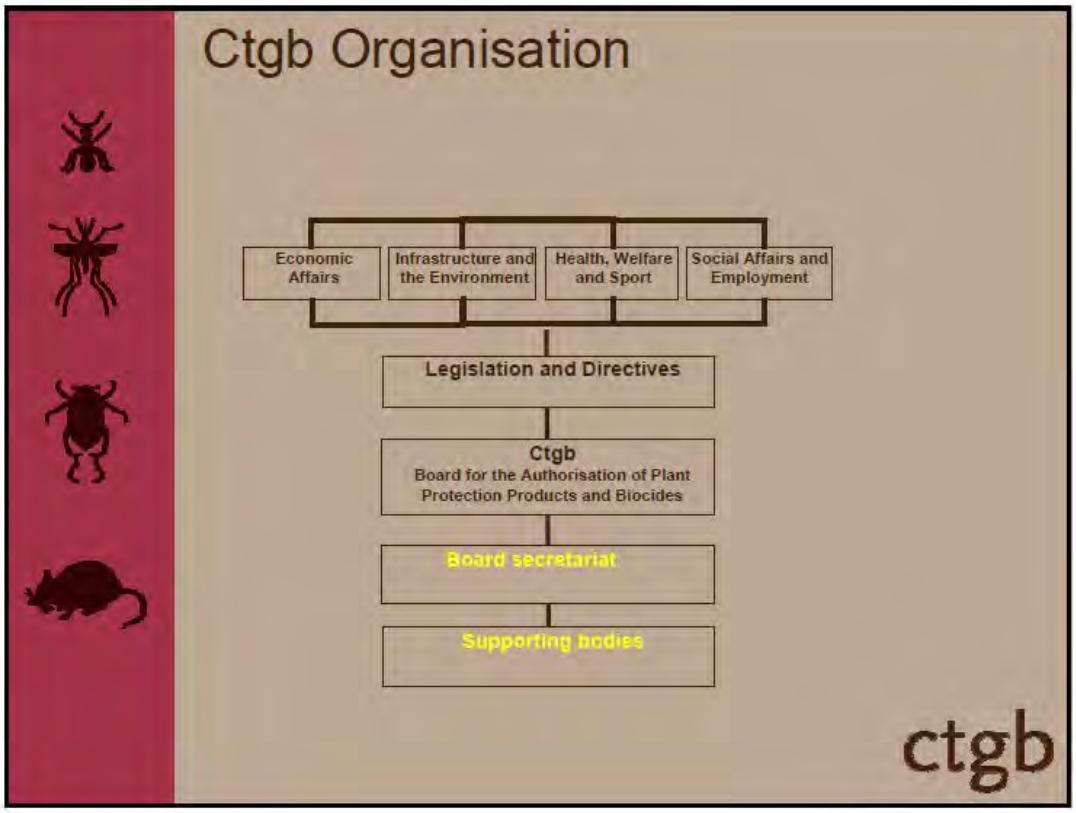

Policy advice
• Advising the ministries responsible for PPP and biocides on national and European authorisation policy
• Ministry of Economic Affairs:
→ Plant protection products
• Ministry of Infrastructure and the Environment:
→ Biocides
ctgb

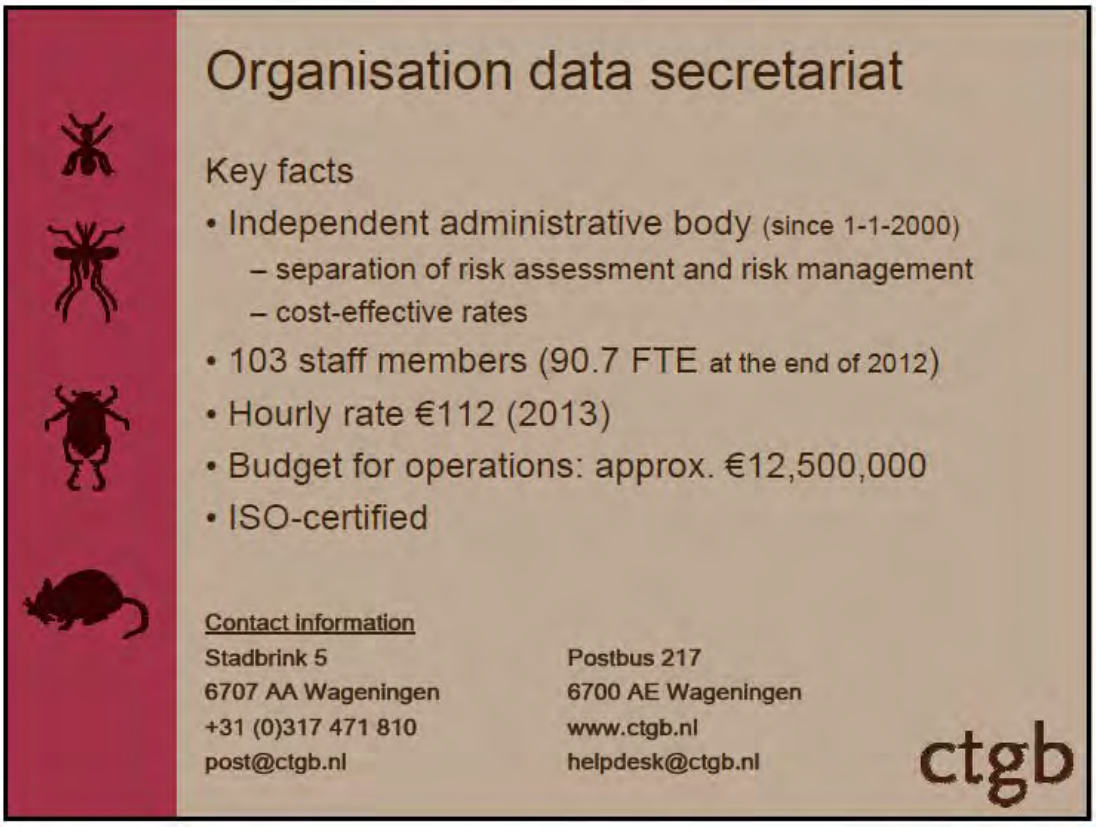

Board
• Independent
• Appointed by the minister of Economic Affairs for 4 years, renewable for 2 times 4 years
• Members cover different disciplines
• Chairman responsible for the overall decisionmaking proces, external contacts (government, stakeholders)
ctgb

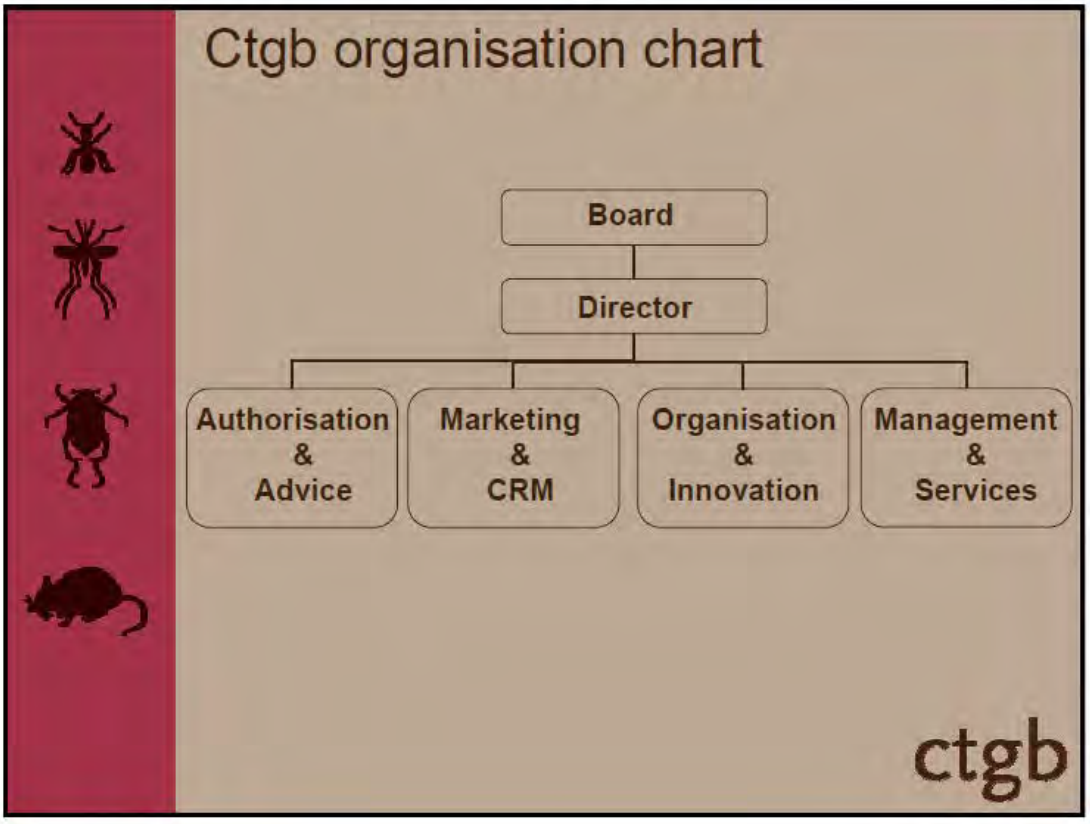

Board
• Members:
•Mr. ir. J.F. de Leeuw (voorzitter)
•Mr. ir. P.A.E. van Erkelens (plv. voorzitter)
•Mrs. dr.ir. E. den Belder
•Mrs. prof.dr. A.J. Murk
•Vacancy
• Deputy Members:
•Mr. dr.ir. R. Houba
•Mr. drs. A.W. van der Wielen
•Mr. dr. ir. W.A.J. de Milliano
•Vacancy
ctgb

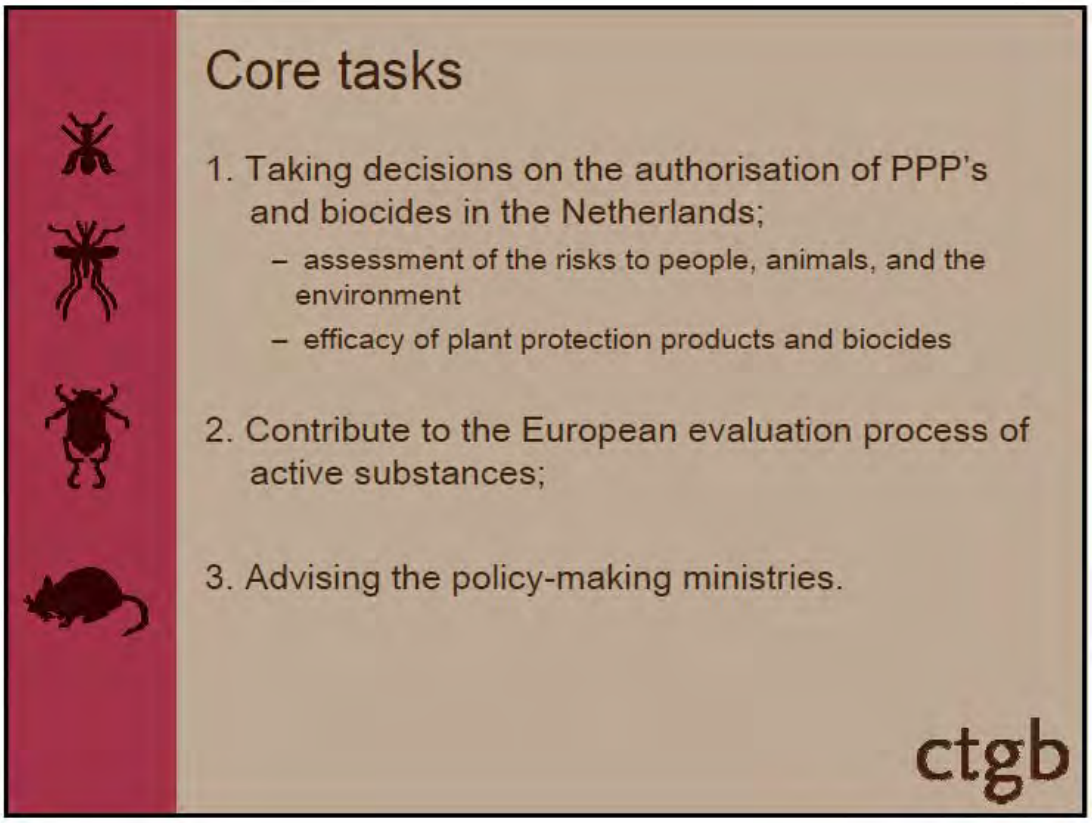

Goals for the coming period
• Responding to the growing amount of applications
• Reasonable costs
• Shorter lead-time
• Maintain/strengthen position in Europe
• Niche: specialty crops
ctgb

2 Presentation made by Dr. ir. L.P. van Duijn, Secretariat / Director




Organisation data secretariat
Key facts
• Independent administrative body (since 1-1-2000)
– separation of risk assessment and risk management
– cost-effective rates
• 103 staff members (90.7 FTE at the end of 2012)
• Hourly rate €112 (2013)
• Budget for operations: approx. €12,500,000
• ISO-certified
Contact information
Stadbrink 5
6707 AA Wageningen
+31 (0)317 471 810
post@ctgb.nl
Postbus 217
6700 AE Wageningen
www.ctgb.nl
helpdesk@ctgb.nl
ctgb


Ctgb organisation chart
Board
Director
Authorisation & Advice
Marketing & CRM
Organisation & Innovation
Management & Services
ctgb


Core tasks
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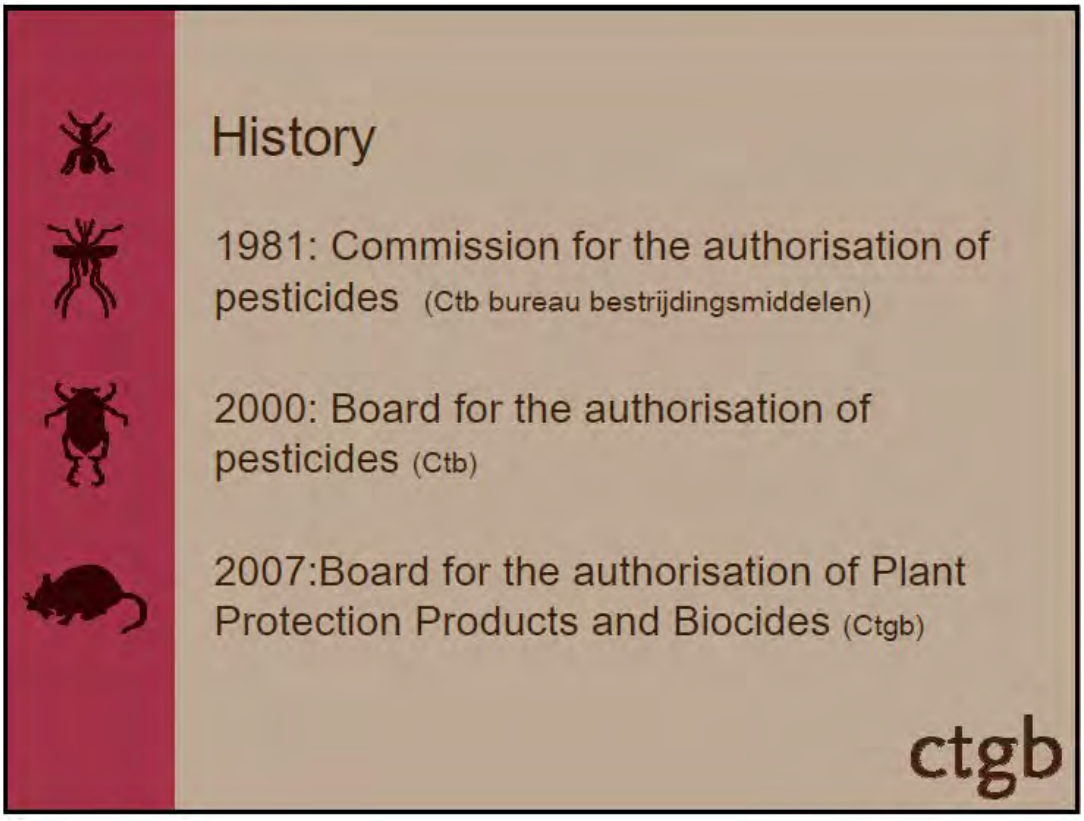
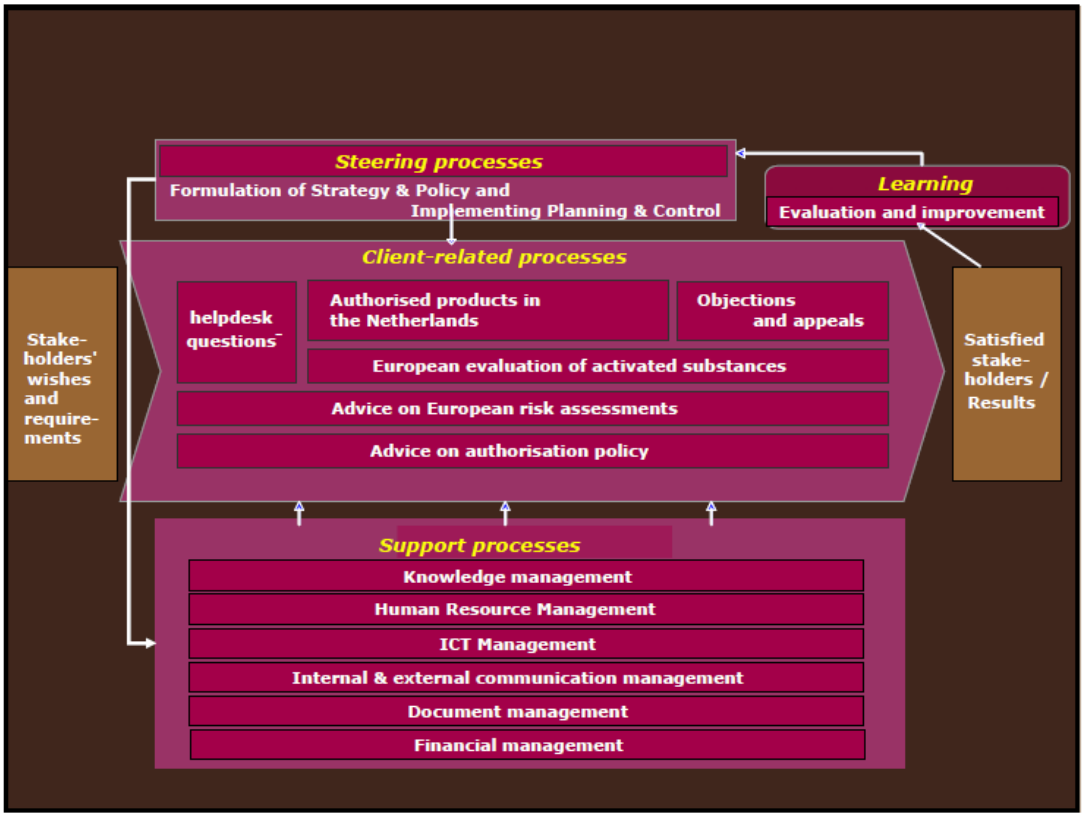
– assessment of the risks to people, animals, and the environment
– efficacy of plant protection products and biocides
2. Contribute to the European evaluation process of active substances;
3. Advising the policy-making ministries.
ctgb


History
1981: Commission for the authorisation of pesticides (Ctb bureau bestrijdingsmiddelen)
2000: Board for the authorisation of pesticides (Ctb)
2007:Board for the authorisation of Plant Protection Products and Biocides (Ctgb)
ctgb


Legal setting
European council directives and regulations
National Acts and Resolutions
Regulations
Economic Affairs
Infrastructure and the Environment
Health, Welfare and Sport
Social Affairs and Employment
ctgb
College voor de toelating van gewasbeschermingsmiddelen en biociden
Regulations and Operating procedures
ctgb


Steering processes
Formulation of Strategy & Policy and Implementing Planning & Control
Learning
Evaluation and improvement
Client-related processes
helpdesk questions
Authorised products in the Netherlands
Objections and appeals
European evaluation of activated substances
Advice on European risk assessments
Advice on authorisation policy
Stake-holders' wishes and require-ments
Satisfied stake-holders / Results
Support processes
Knowledge management
Human Resource Management
ICT Management
Internal & external communication management
Document management
Financial management

HISTORY
European Council Directive 91/414/EEC

- Harmonise registration.
- Regulate active substances
- Set basic product safety standards
- Harmonize MRLs (396/2005)

Active substances approved at Community level.

Products approved at Member state level.

ctgb

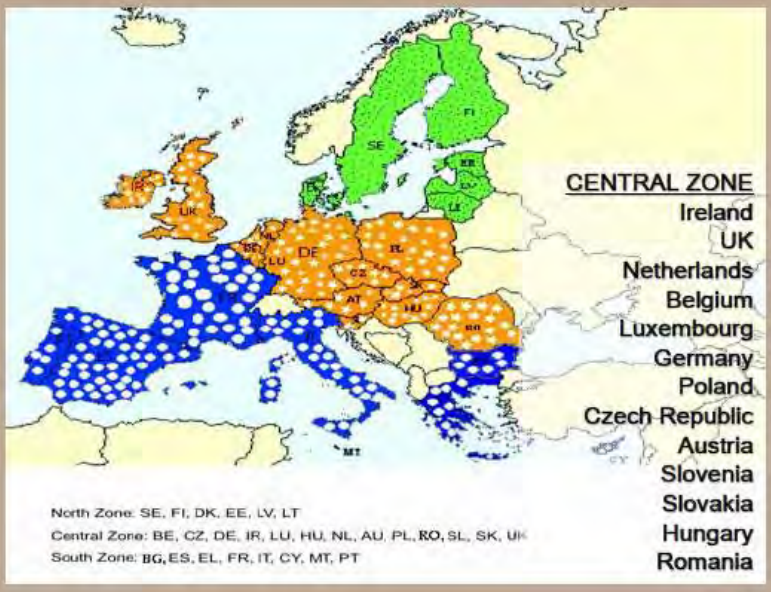
European council regulation 1107/2009

Regulation for the placing of plant protection products on the market

Framework directive Sustainable use of pesticides

ctgb

3 Zones



ctgb

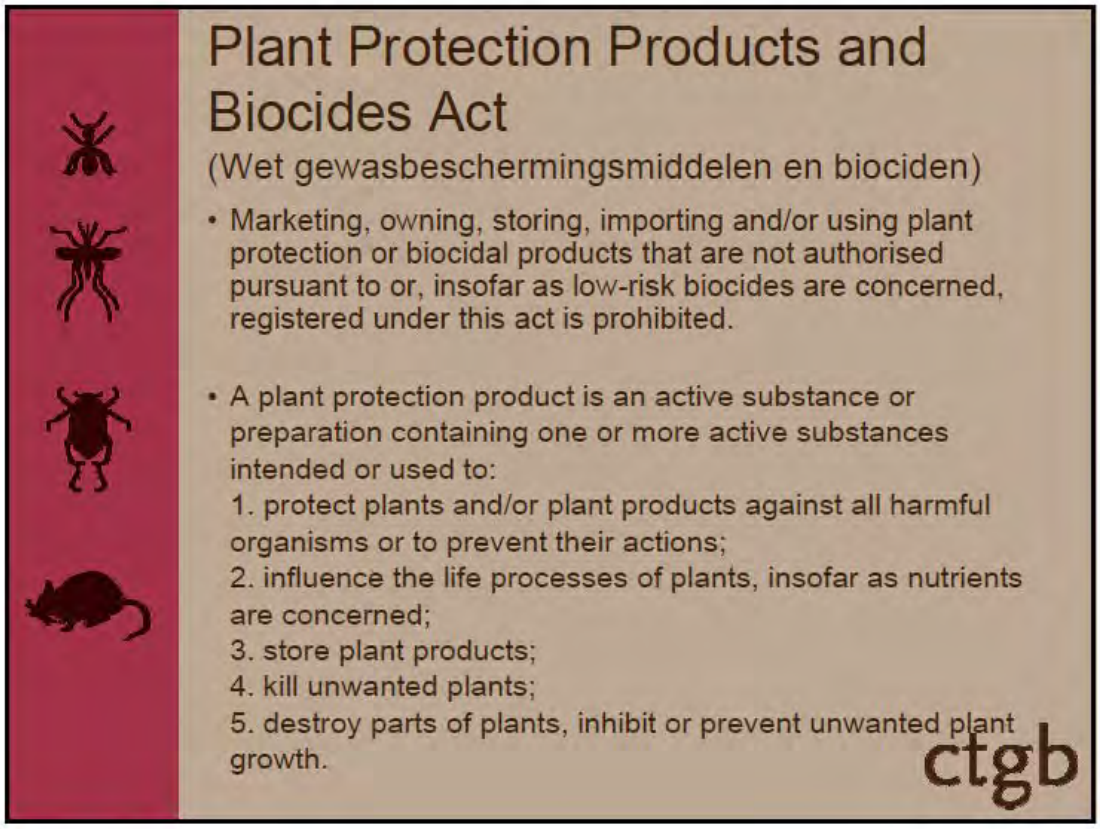
Dutch authorisations

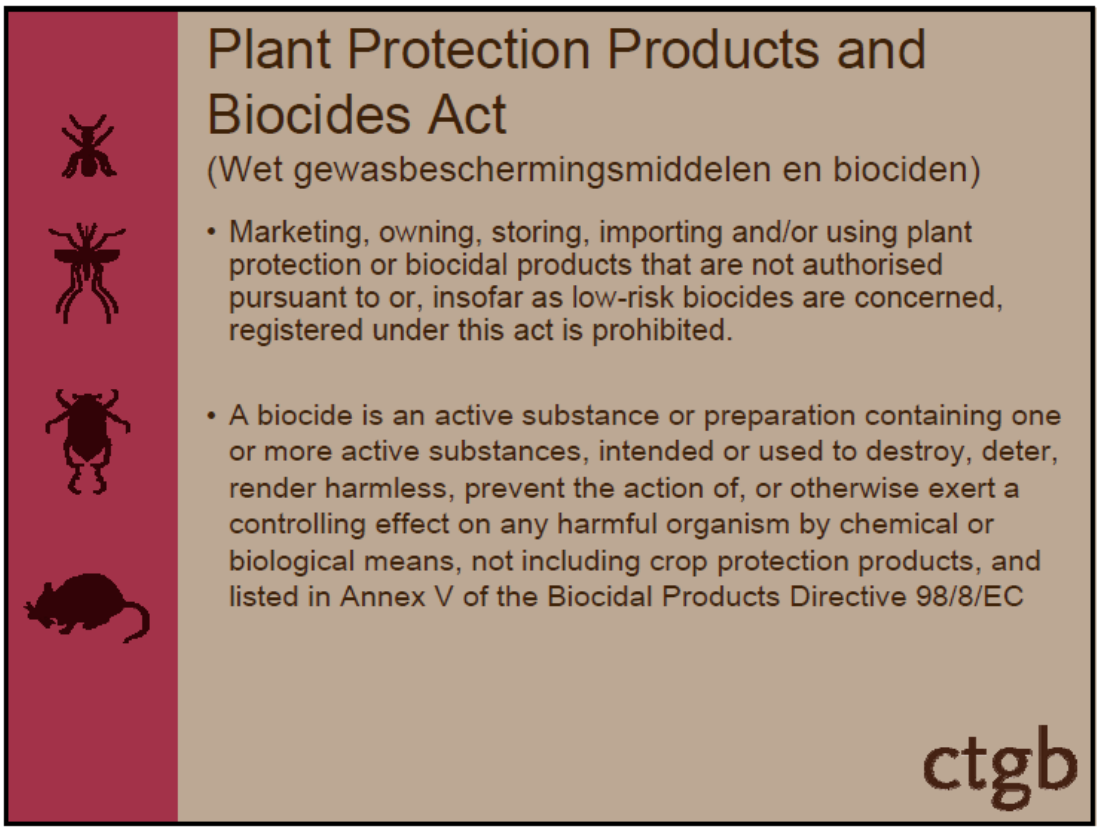
- National legislation and regulations:
- EU regulations: European council Regulation 1107/2009 concerning placing of PPP on the market and Directive 98/8/EC concerning the marketing of biocidal products

Authorisation process

- Application for authorisation
- Assessment criteria: physical chemical properties, analytical methods, environment, efficacy, toxicology and residues
- Legal Instructions for Use and Directions for Use (WGGA)
- Decision

ctgb


Plant Protection Products and Biocides Act
(Wet gewasbeschermingsmiddelen en biociden)
• Marketing, owning, storing, importing and/or using plant protection or biocidal products that are not authorised pursuant to or, insofar as low-risk biocides are concerned, registered under this act is prohibited.
• A plant protection product is an active substance or preparation containing one or more active substances intended or used to:
1. protect plants and/or plant products against all harmful organisms or to prevent their actions;
2. influence the life processes of plants, insofar as nutrients are concerned;
3. store plant products;
4. kill unwanted plants;
5. destroy parts of plants, inhibit or prevent unwanted plant growth.
ctgb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• Marketing, owning, storing, importing and/or using plant protection or biocidal products that are not authorised pursuant to or, insofar as low-risk biocides are concerned, registered under this act is prohibited.
• A biocide is an active substance or preparation containing one or more active substances, intended or used to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means, not including crop protection products, and listed in Annex V of the Biocidal Products Directive 98/8/EC
ctgb

Authorisation process

- Administrative completeness
- Intake process/scientific completeness
- Evaluation & summarising
- Risk assessment

- Approval / Rejection
  - –or Additional information needed

ctgb

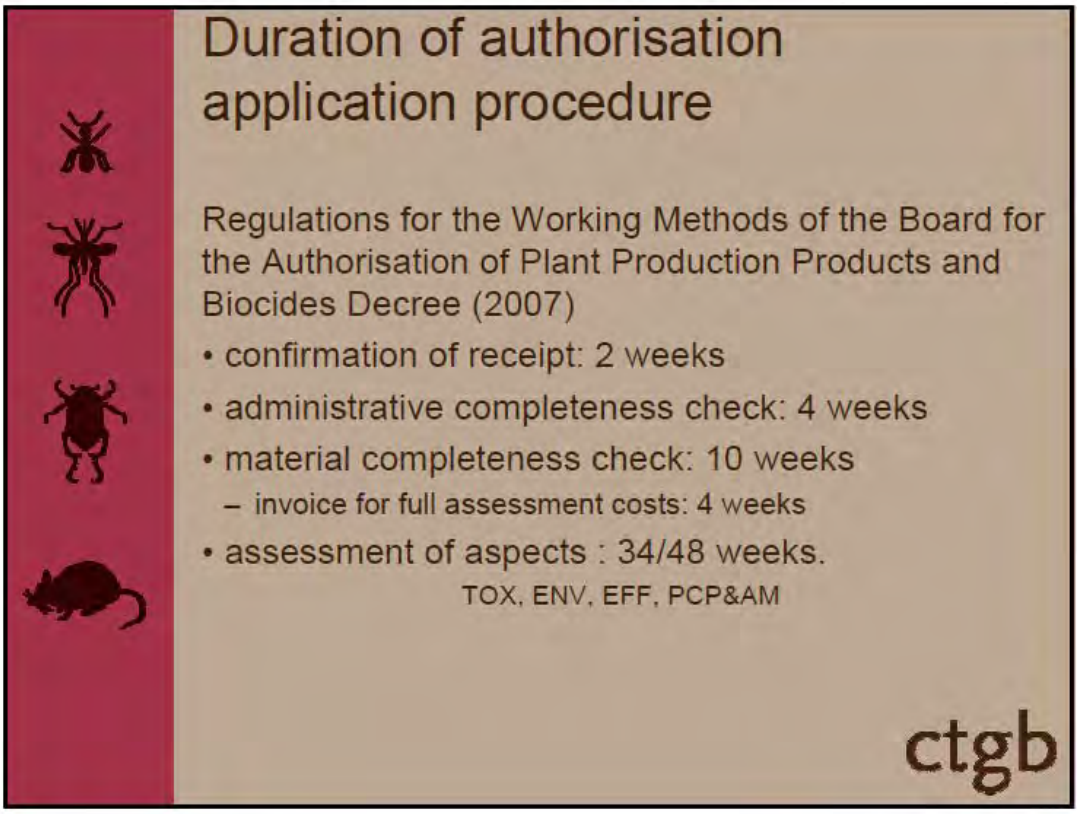
Application for authorisation

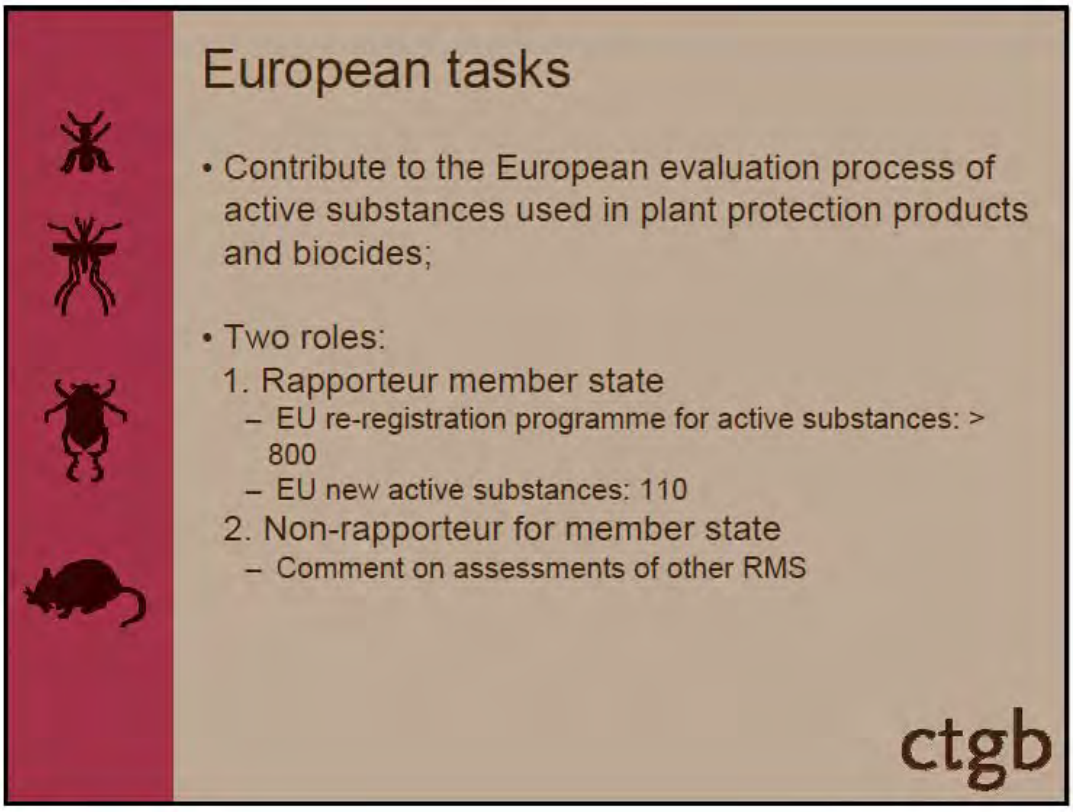
Applicant is the product manufacturer

- Application costs
- Application form
  - – www.ctgb.nl

- Application file CD-ROM + paper
  - – Product file
  - – Substance file

ctgb


Duration of authorisation application procedure
Regulations for the Working Methods of the Board for the Authorisation of Plant Production Products and Biocides Decree (2007)
• confirmation of receipt: 2 weeks
• administrative completeness check: 4 weeks
• material completeness check: 10 weeks
– invoice for full assessment costs: 4 weeks
• assessment of aspects : 34/48 weeks.
TOX, ENV, EFF, PCP&AM
ctgb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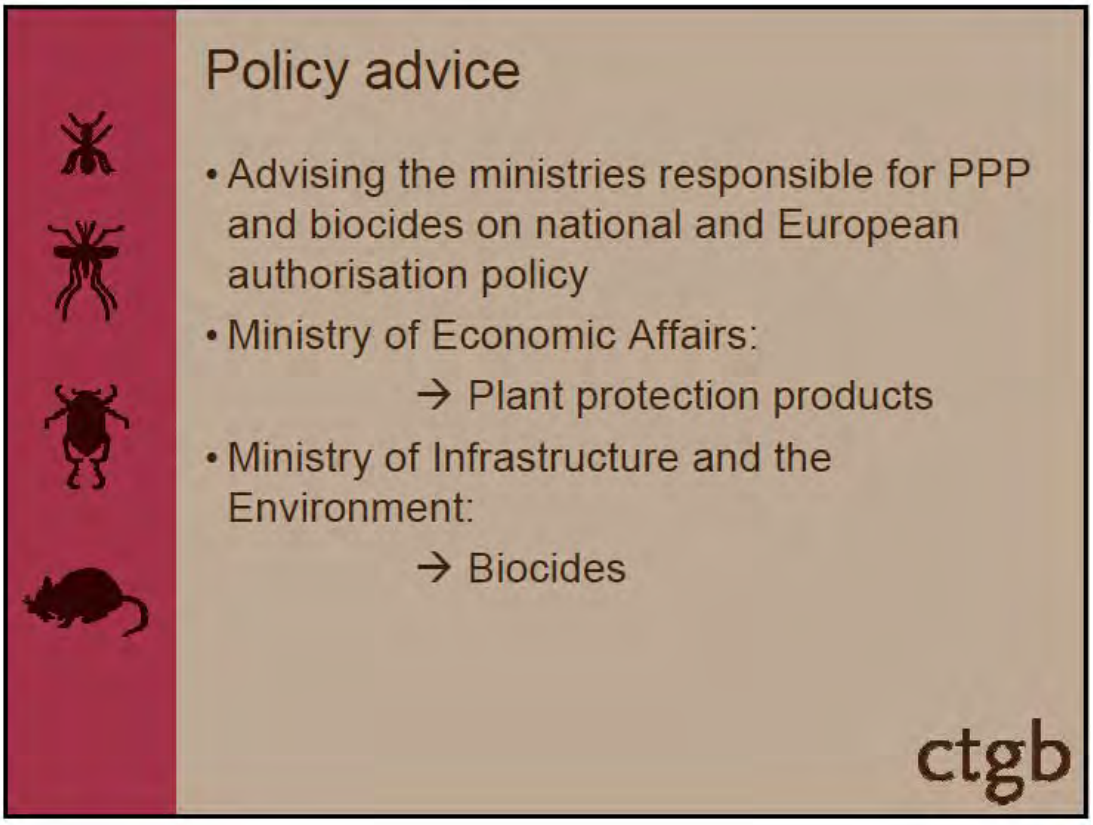
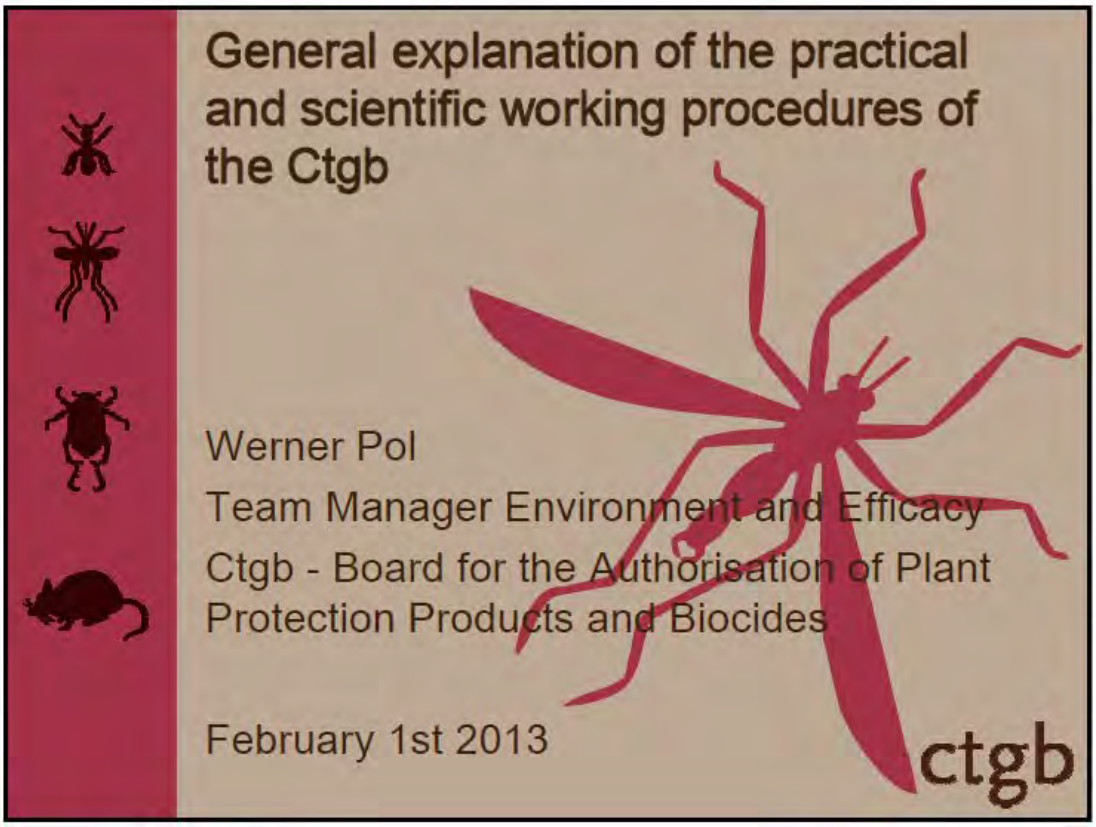
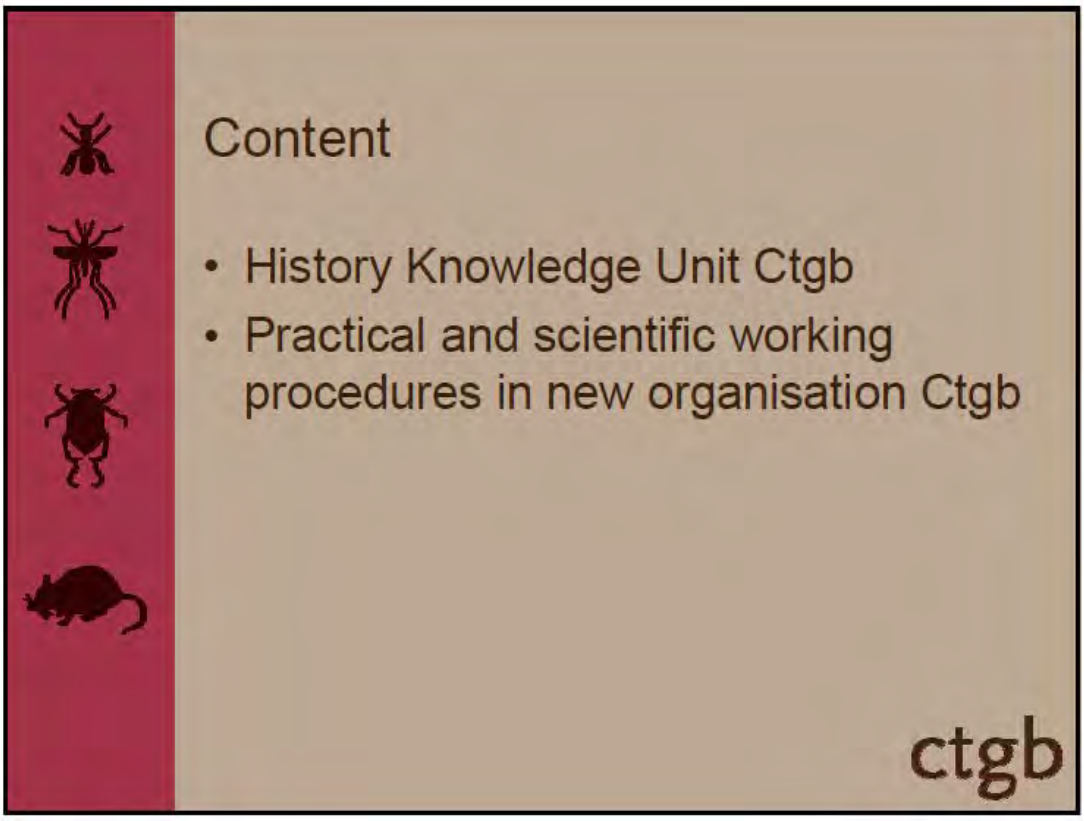
– EU new active substances: 110
2. Non-rapporteur for member state
– Comment on assessments of other RMS
ctgb

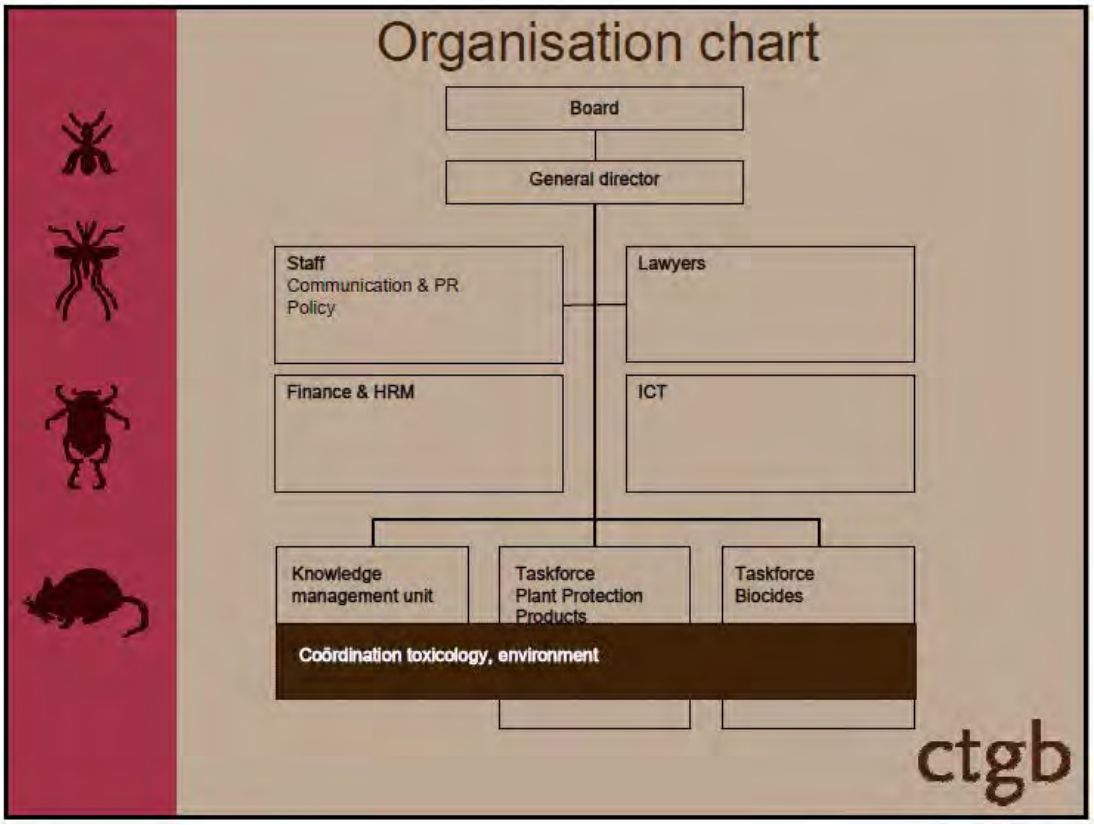

Policy advice
• Advising the ministries responsible for PPP and biocides on national and European authorisation policy
• Ministry of Economic Affairs:
→ Plant protection products
• Ministry of Infrastructure and the Environment:
→ Biocides
ctgb

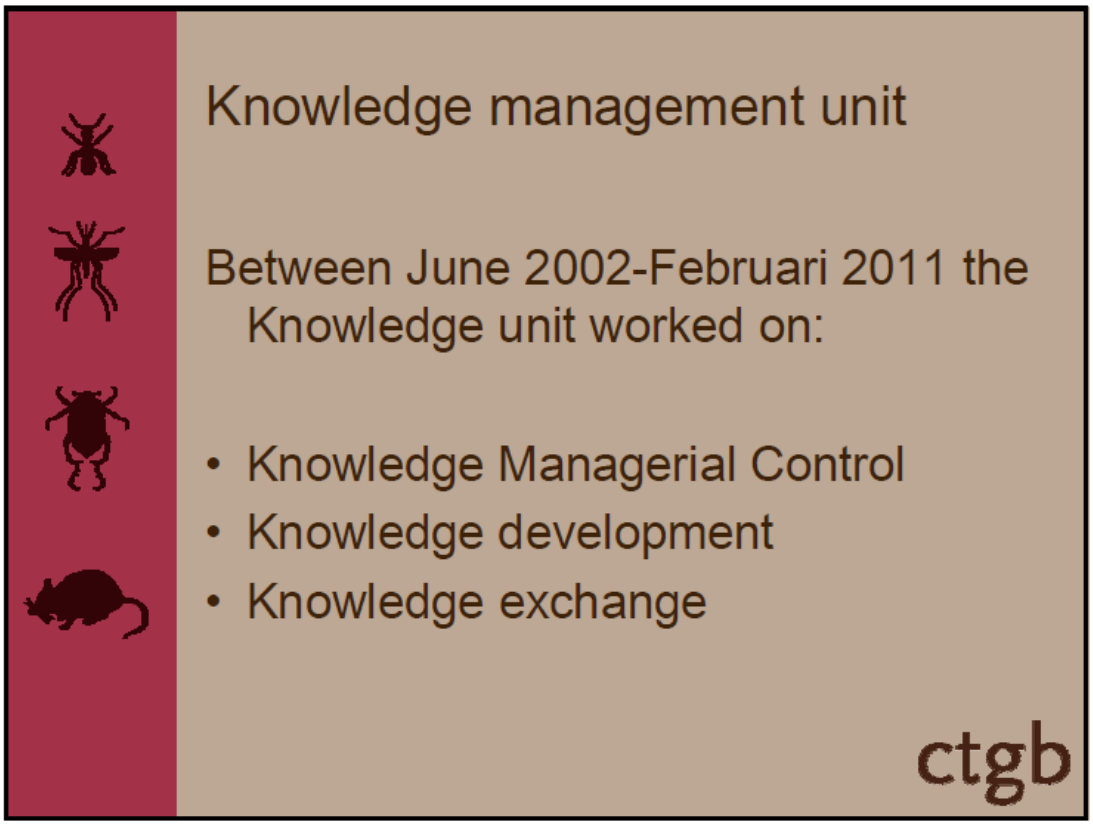

Challenges for the future
• Changing attitude general public and parlement
• How to deal with "emerging knowledge"
• European playing field
ctgb

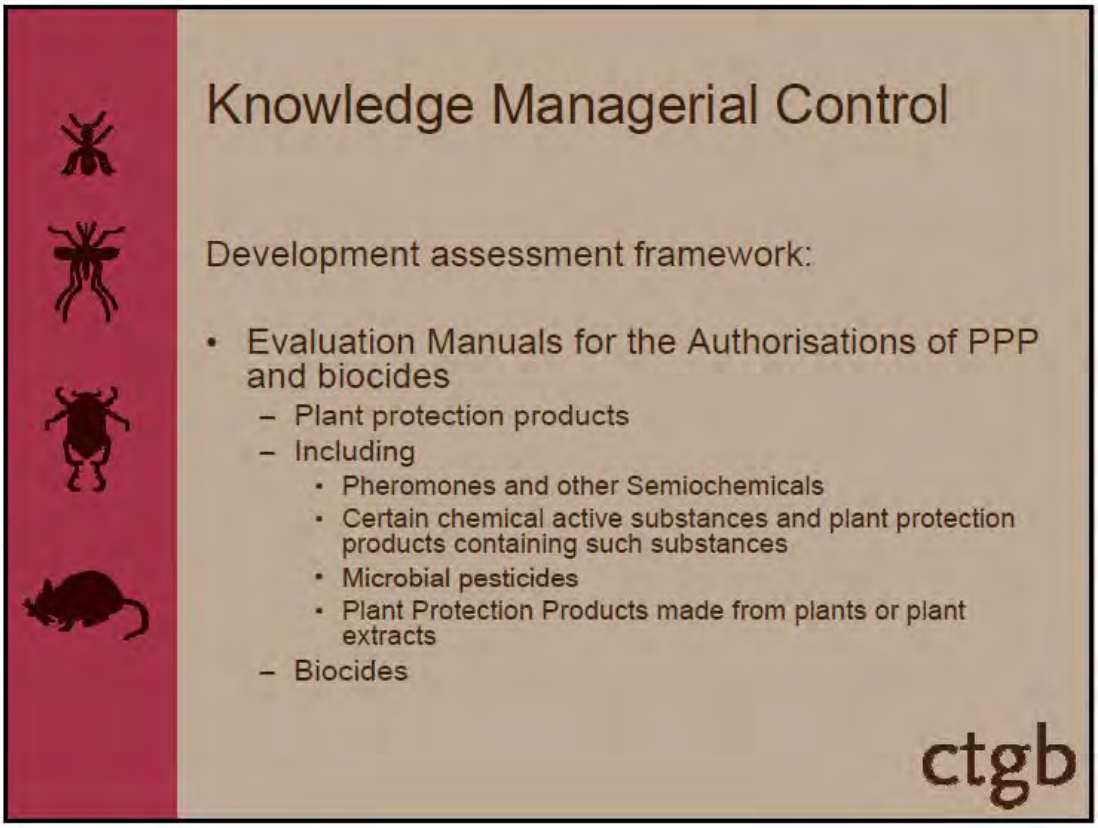
3 Presentation of Mr Werner Pol, Team Manager Environmental Assessment

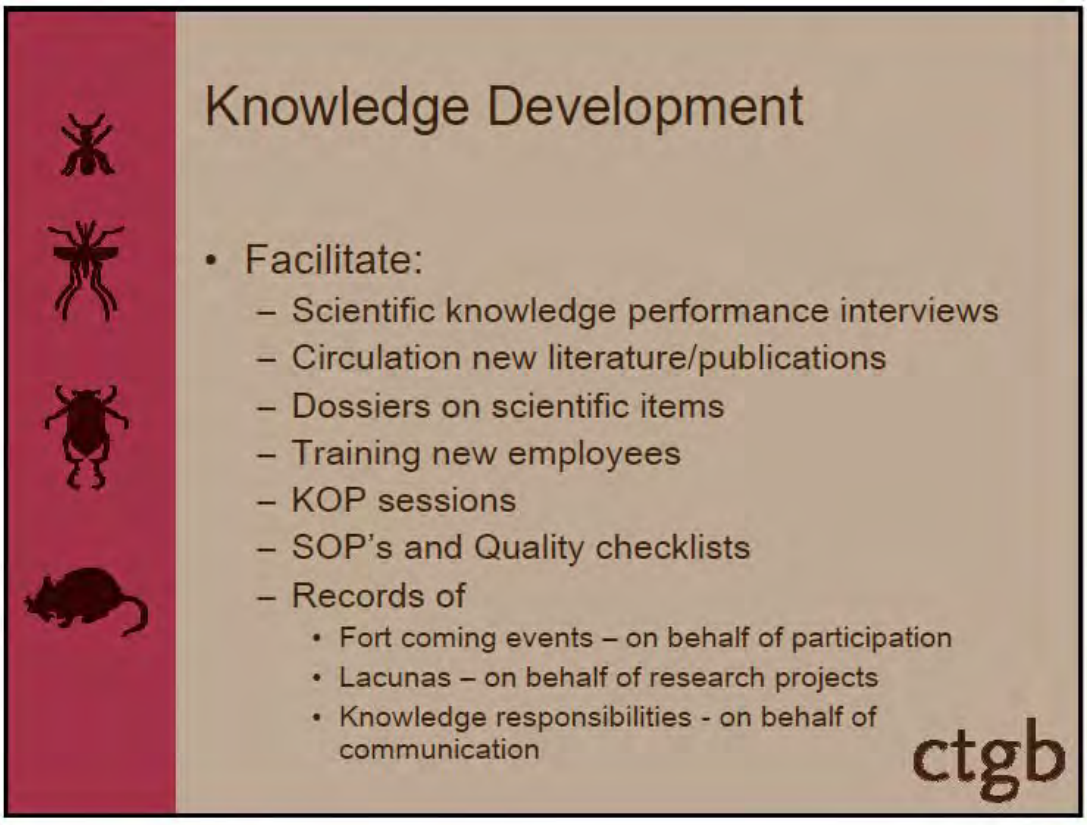


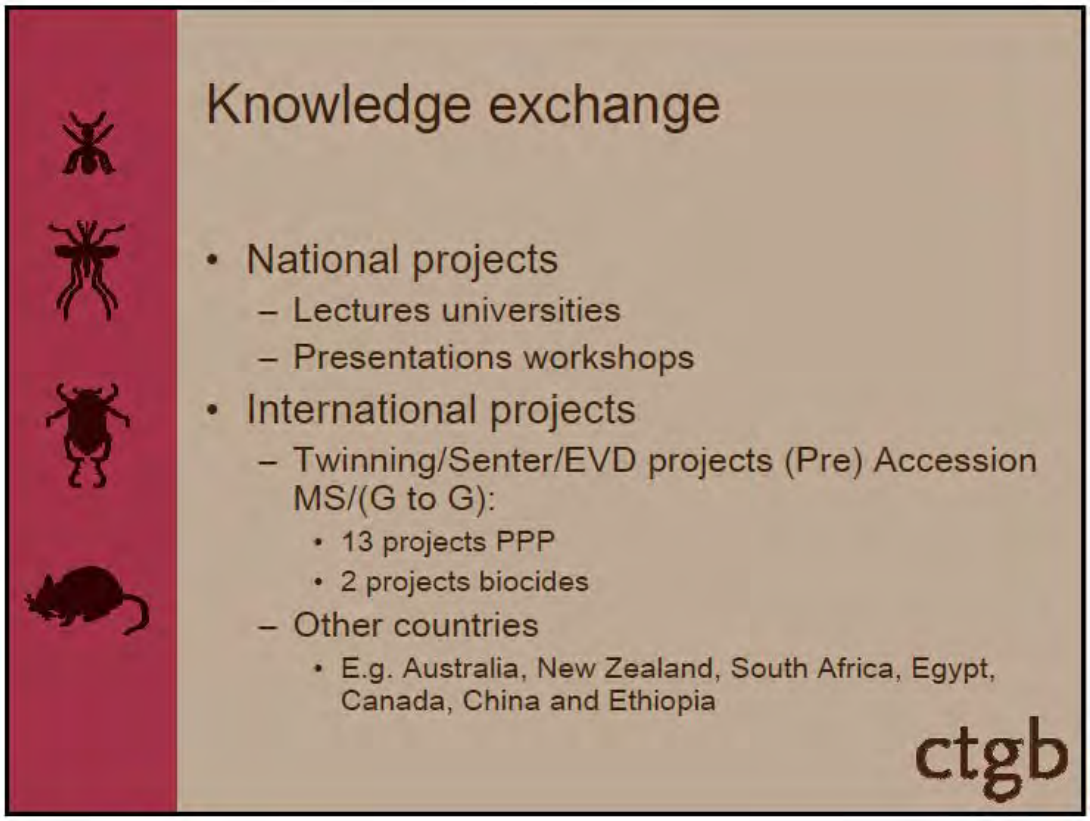


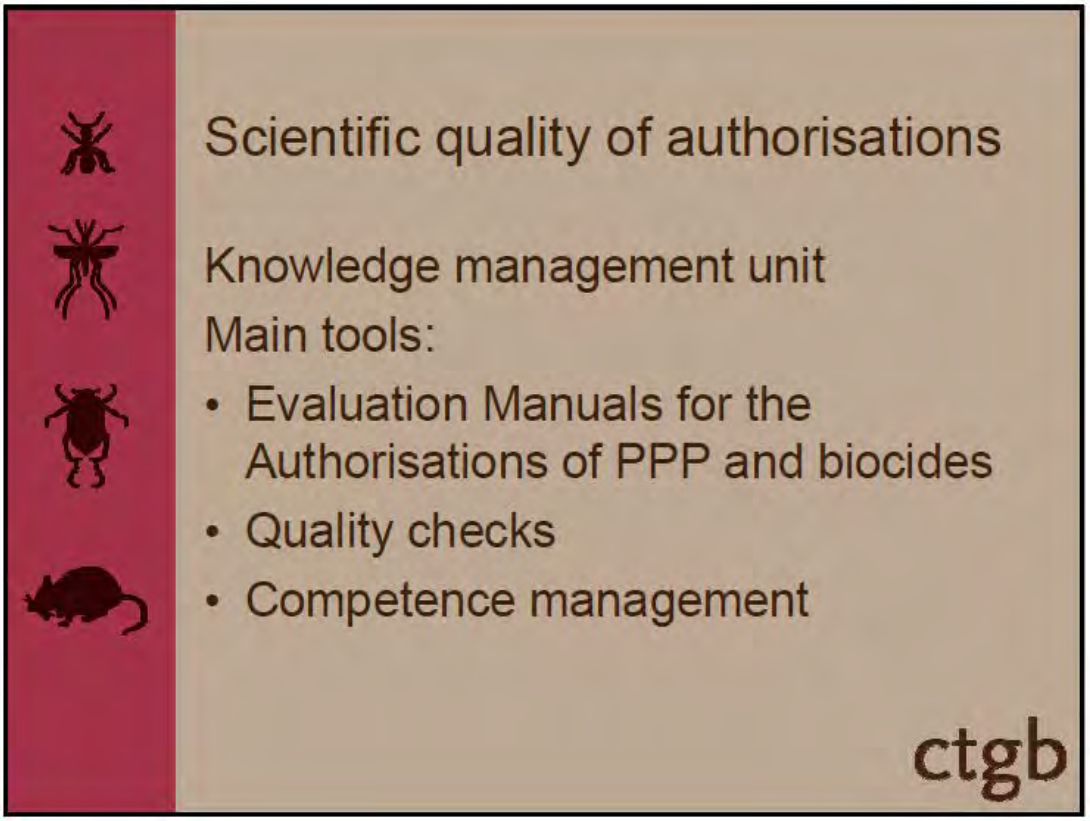

Organisation chart
Board
General director
Staff
Communication & PR
Policy
Lawyers
Finance & HRM
ICT
Knowledge management unit
Taskforce Plant Protection Products
Taskforce Biocides
Coördination toxicology, environment
ctgb


Knowledge management unit
Between June 2002-Februari 2011 the Knowledge unit worked on:
• Knowledge Managerial Control
• Knowledge development
• Knowledge exchange
ctgb


Knowledge Managerial Control
Development assessment framework:
• Evaluation Manuals for the Authorisations of PPP and biocides
– Plant protection products
– Including
• Pheromones and other Semiochemicals
• Certain chemical active substances and plant protection products containing such substances
• Microbial pesticides
• Plant Protection Products made from plants or plant extracts
– Biocides
ctgb


Knowledge Development
• Facilitate:
– Scientific knowledge performance interviews
– Circulation new literature/publications
– Dossiers on scientific items
– Training new employees
– KOP sessions
– SOP's and Quality checklists
– Records of
• Fort coming events – on behalf of participation
• Lacunas – on behalf of research projects
• Knowledge responsibilities - on behalf of communication
ctgb


Knowledge exchange
• National projects
– Lectures universities
– Presentations workshops
• International projects
– Twinning/Senter/EVD projects (Pre) Accession MS/(G to G):
• 13 projects PPP
• 2 projects biocides
– Other countries
• E.g. Australia, New Zealand, South Africa, Egypt, Canada, China and Ethiopia
ctgb


Scientific quality of authorisations
Knowledge management unit
Main tools:
• Evaluation Manuals for the Authorisations of PPP and biocides
• Quality checks
• Competence management
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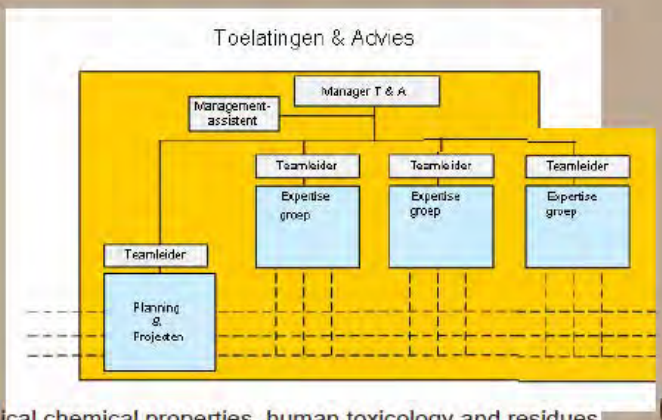
New Organisation

Since February 2011 knowledge is incorporated within the scientific teams of T&A (Authorisation & Advice) (Fourth team per March 1st 2013)



- Physical chemical properties, human toxicology and residues
- Environment and Efficacy

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New organisation

Knowledge development is continued (T&A)

Development assessment framework is responsibility of T&A and O&I

- Implementation assessment framework (procedural)
- Implementation new GD/assessment methodology

⇒ Recording and Implementation new Evaluation Manual

Quality assessment is responsibility of T&A and O&I

Quality Hand Book – Jobaids

Quality check assessments – Checklists

Knowledge Exchange is now responsibility of M&R

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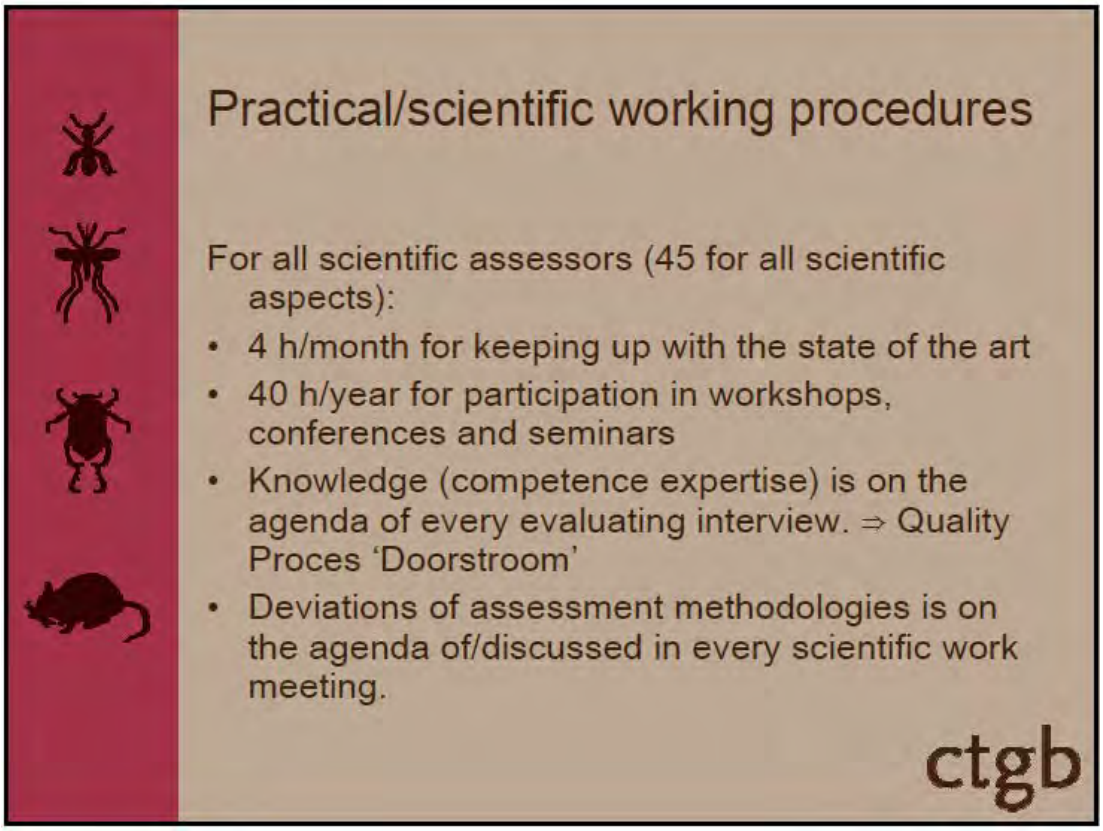
Practical/scientific working procedures
For all scientific assessors (45 for all scientific aspects):
• 4 h/month for keeping up with the state of the art
• 40 h/year for participation in workshops, conferences and seminars
• Knowledge (competence expertise) is on the agenda of every evaluating interview. ⇒ Quality Proces 'Doorstroom'
• Deviations of assessment methodologies is on the agenda of/discussed in every scientific work meeting.
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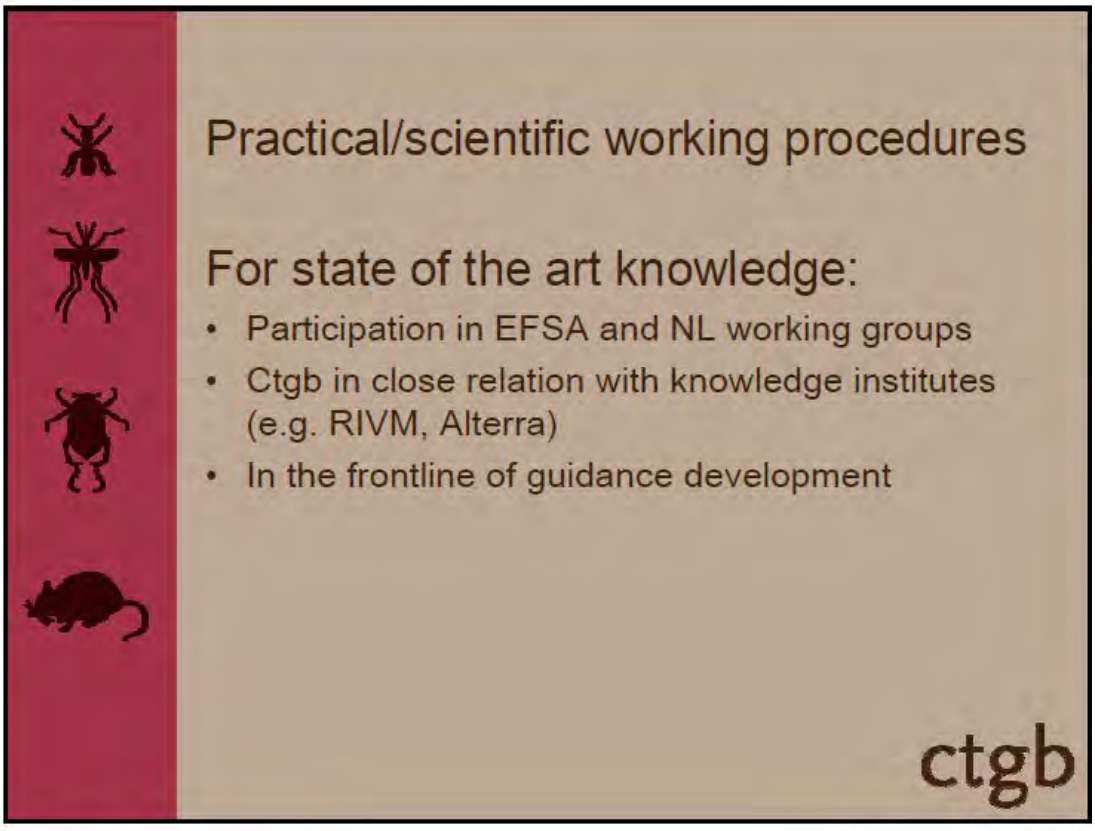
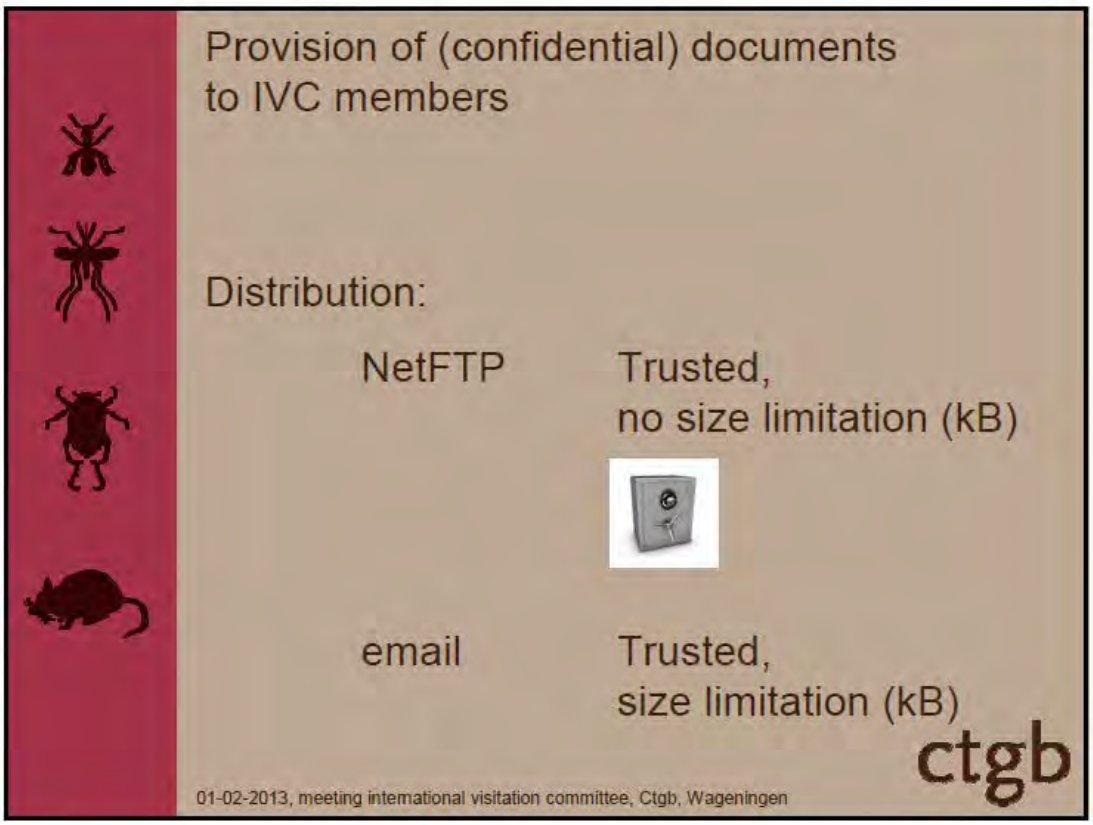
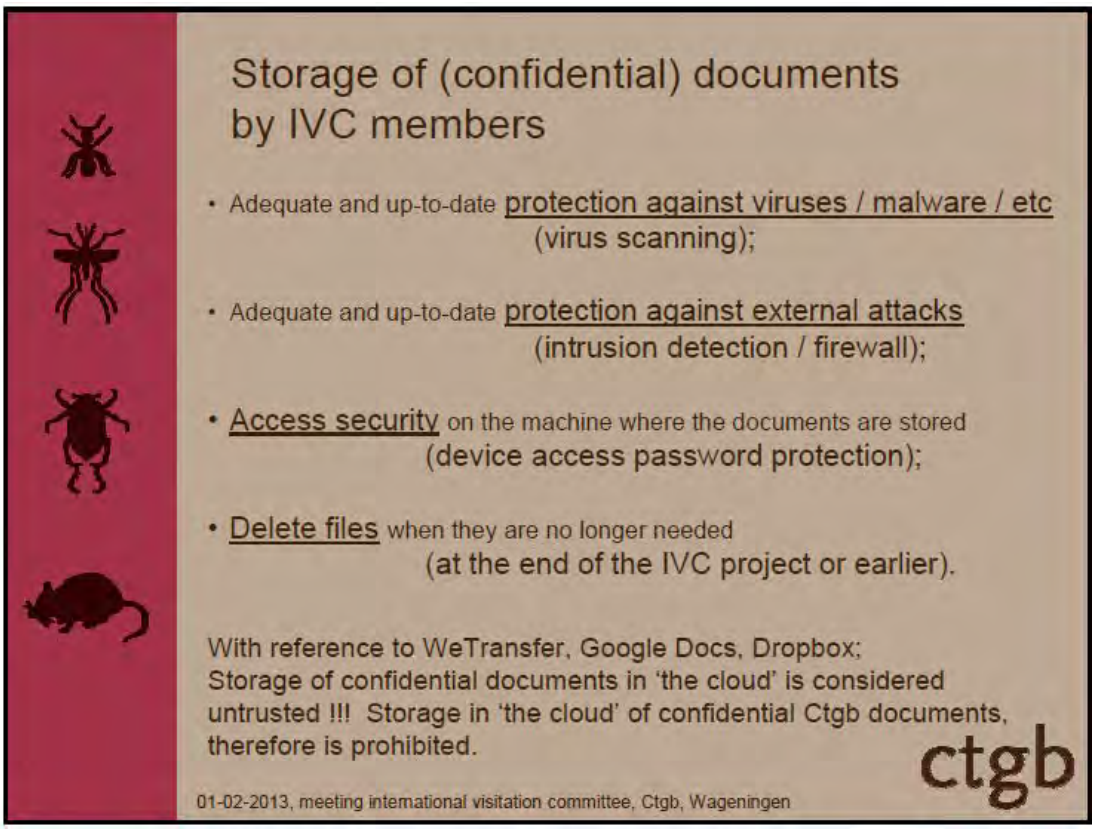

Practical/scientific working procedures
For state of the art knowledge:
• Participation in EFSA and NL working groups
• Ctgb in close relation with knowledge institutes (e.g. RIVM, Alterra)
• In the frontline of guidance development
ctgb


More information at
http://www.ctgb.nl/
ctgb

4 Provision & Handling of Confidential Documentation





Appendix 8: Presentations made by the Chairman, the Director and Senior Staff (Continued)

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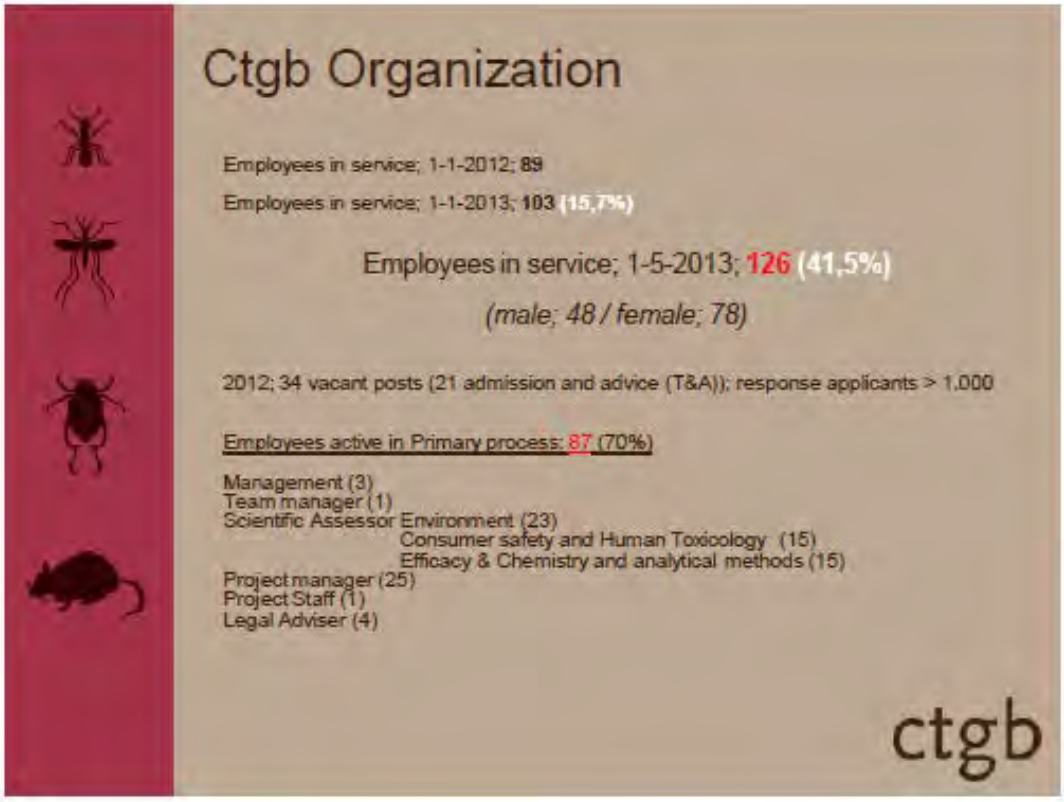
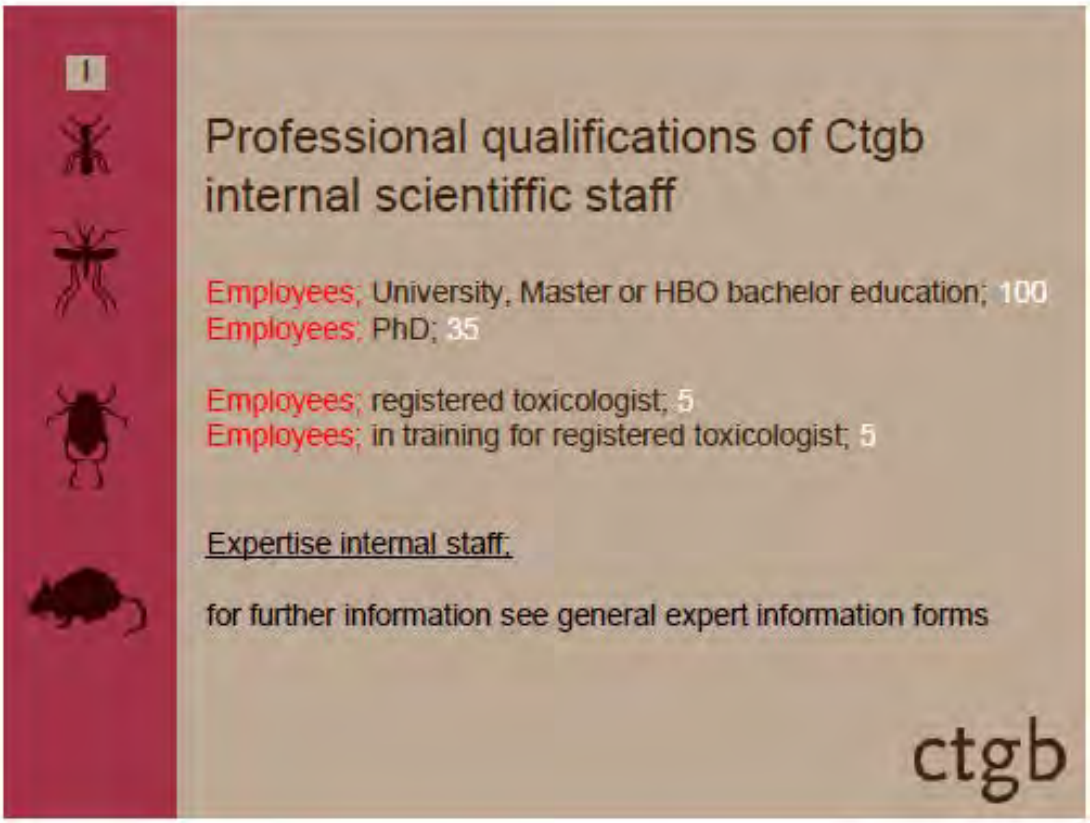
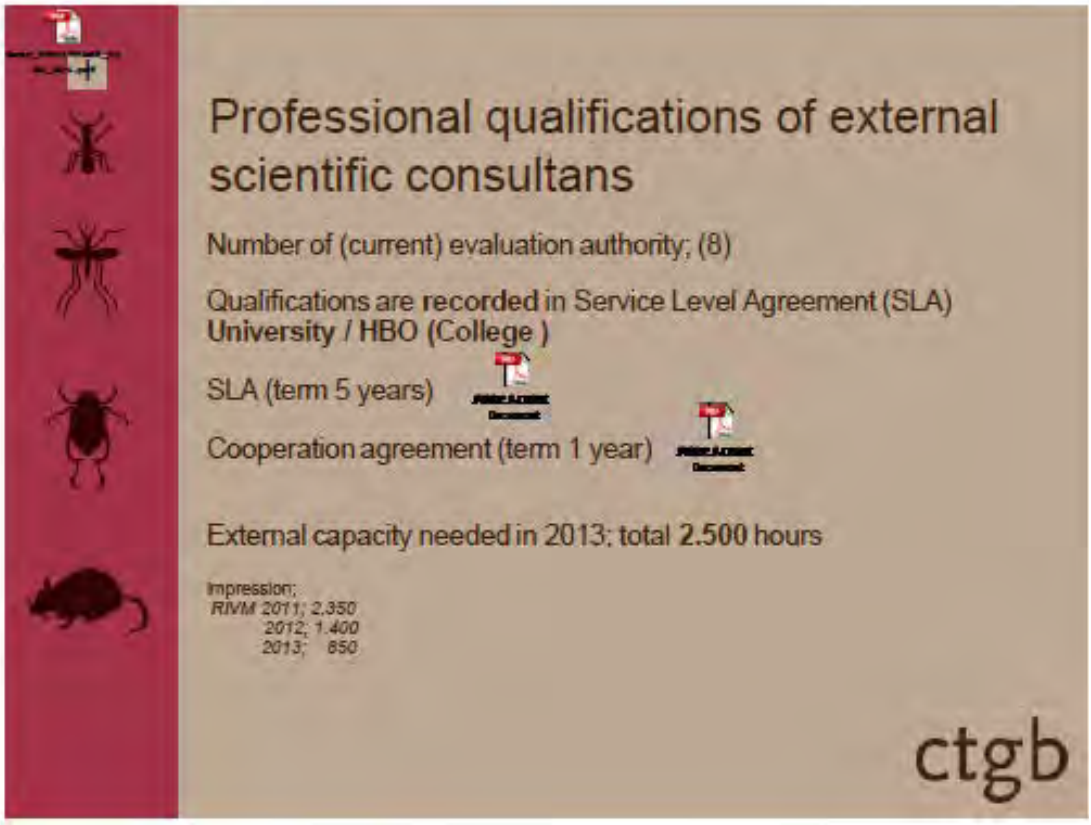
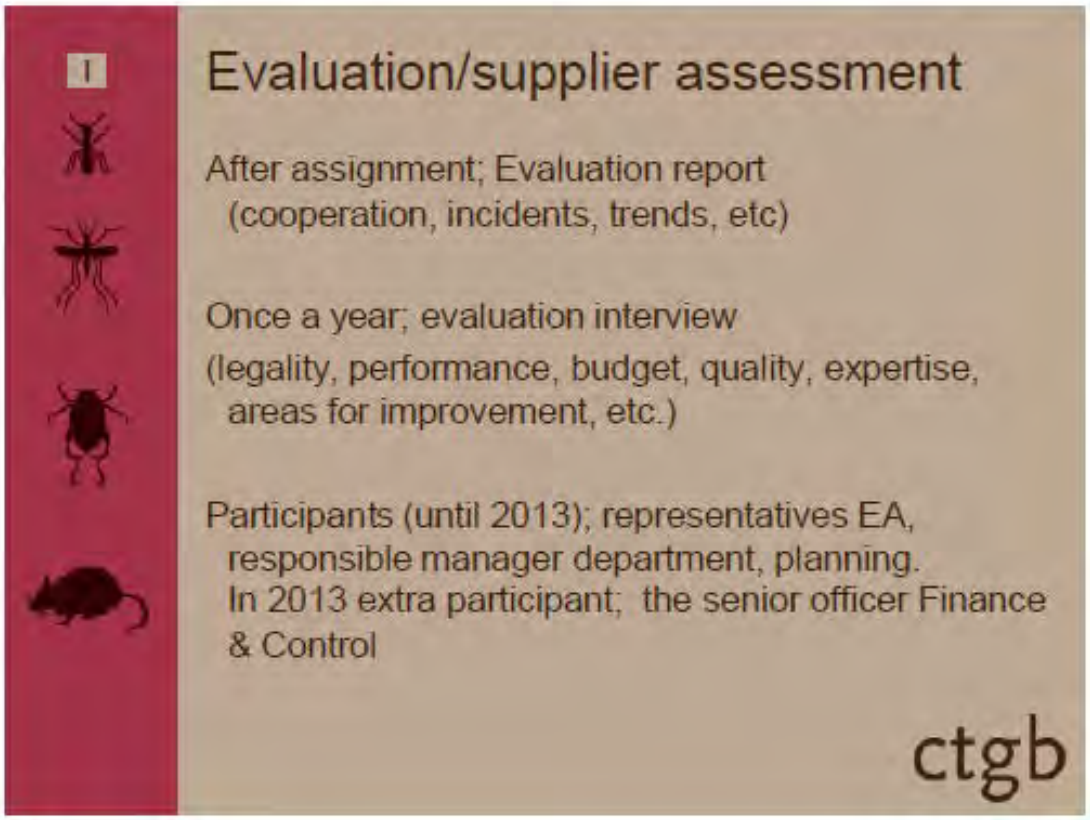
5 Presentation of Mw. Ivonne van Geerenstein-Klarenbeek, Manager Business Operations




Professional qualifications of Ctgb internal scientiffic staff
Employees; University, Master or HBO bachelor education; 100
Employees; PhD; 35
Employees; registered toxicologist; 5
Employees; in training for registered toxicologist; 5
Expertise internal staff;
for further information see general expert information forms
ctgb


Professional qualifications of external scientific consultans
Number of (current) evaluation authority; (8)
Qualifications are recorded in Service Level Agreement (SLA)
University / HBO (College)
SLA (term 5 years)
Cooperation agreement (term 1 year)
External capacity needed in 2013; total 2.500 hours
Impression;
RIVM 2011; 2.350
2012; 1.400
2013; 850
ctgb


Evaluation/supplier assessment
After assignment; Evaluation report (cooperation, incidents, trends, etc)
Once a year; evaluation interview
(legality, performance, budget, quality, expertise, areas for improvement, etc.)
Participants (until 2013); representatives EA, responsible manager department, planning. In 2013 extra participant; the senior officer Finance & Control
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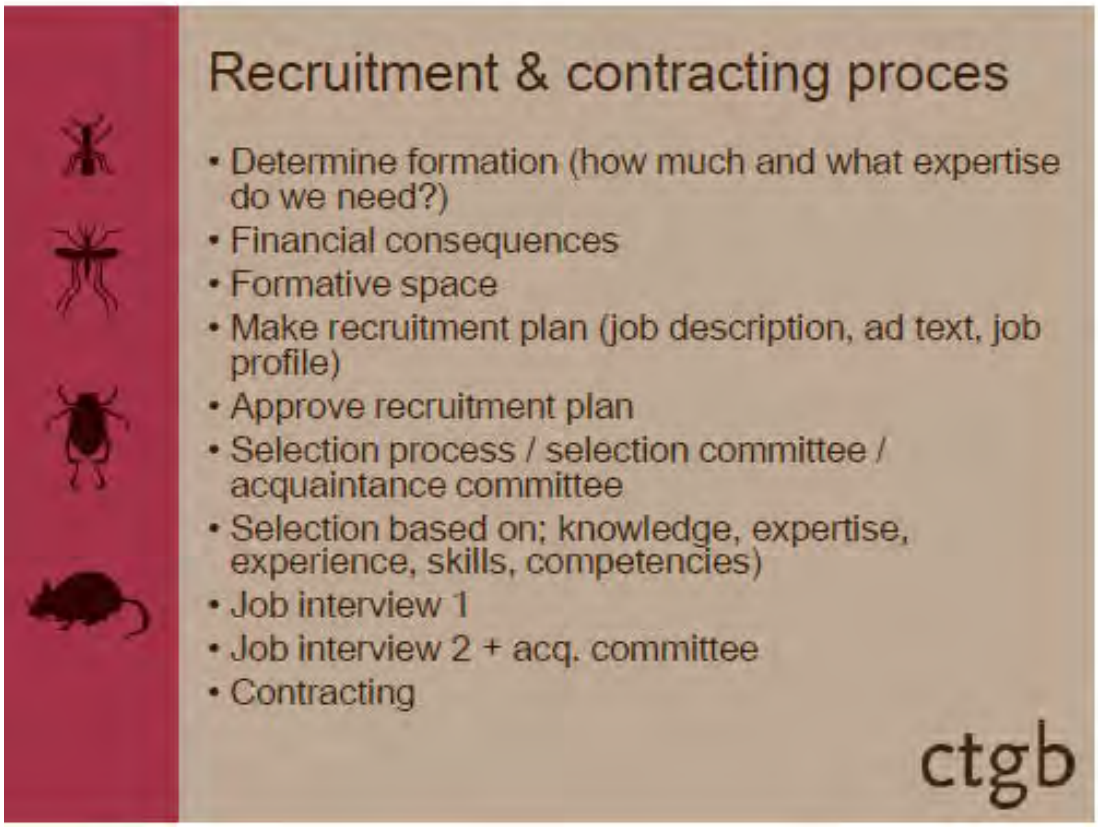
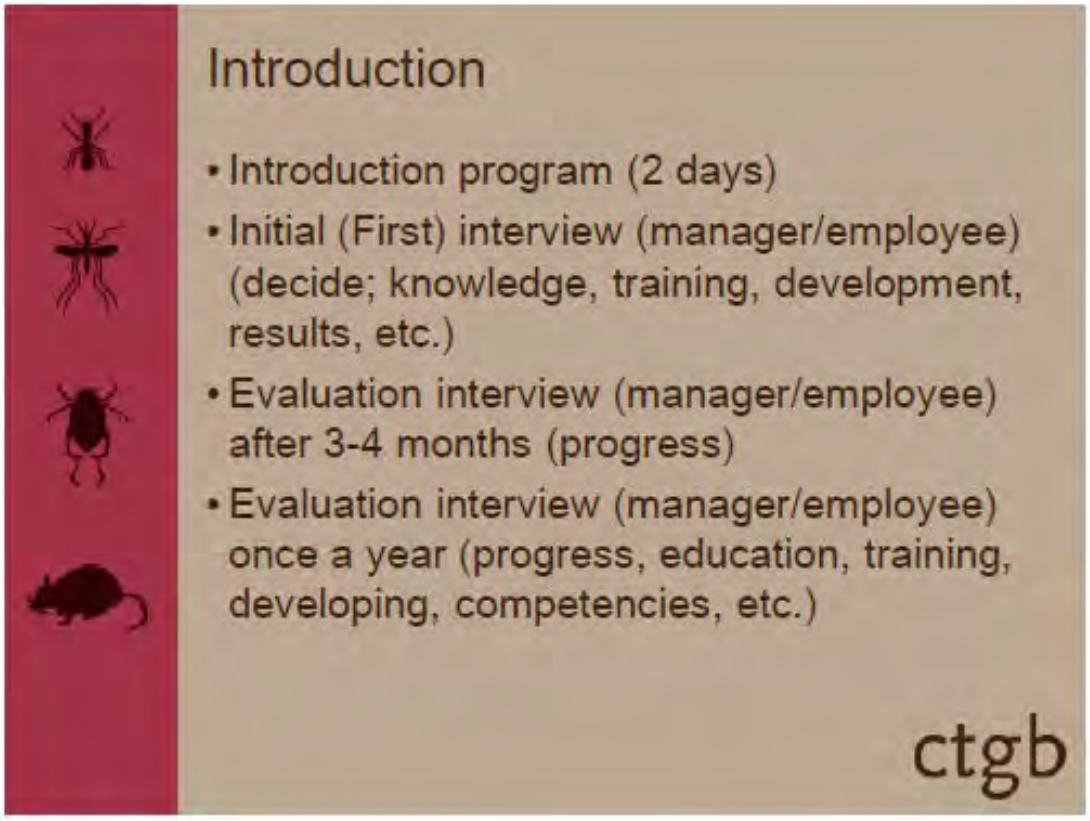
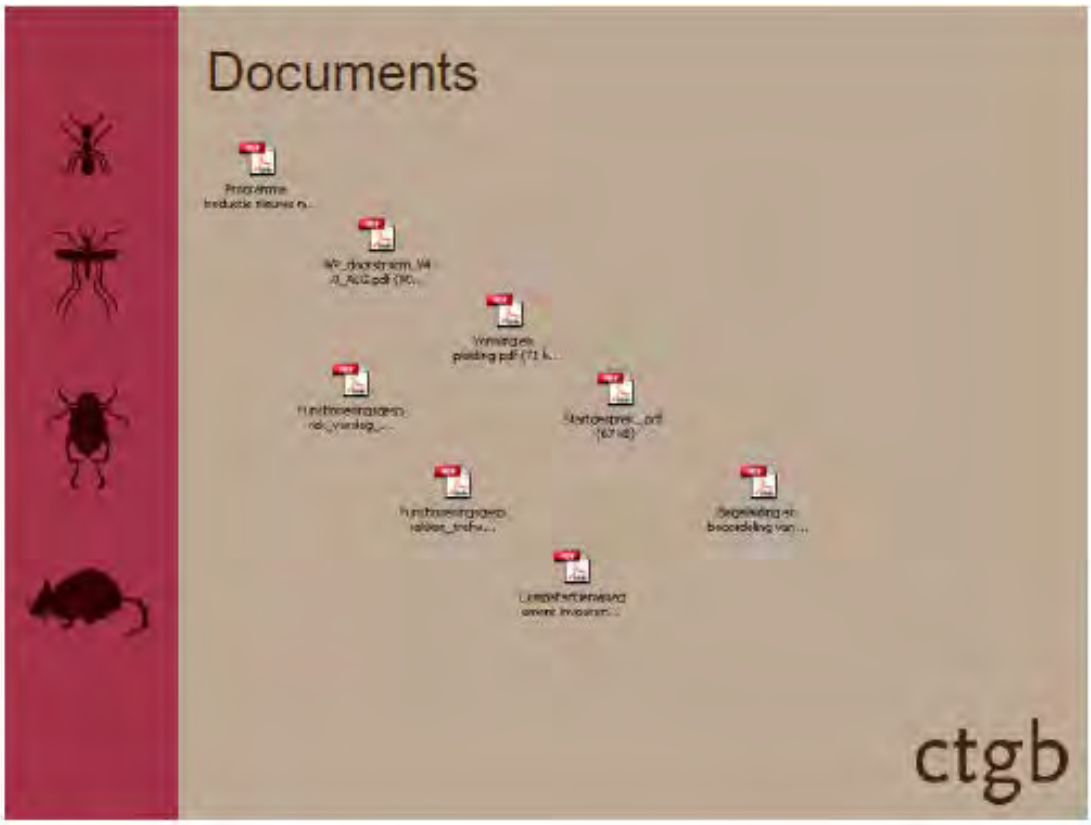
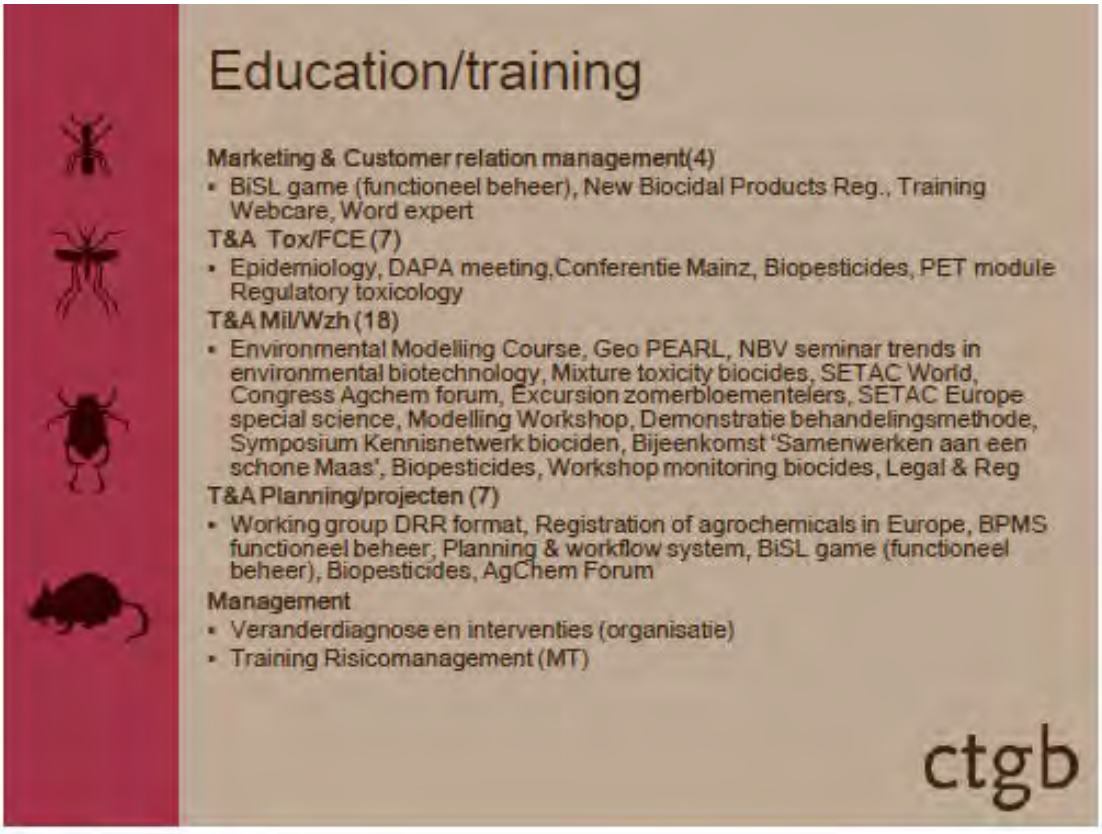
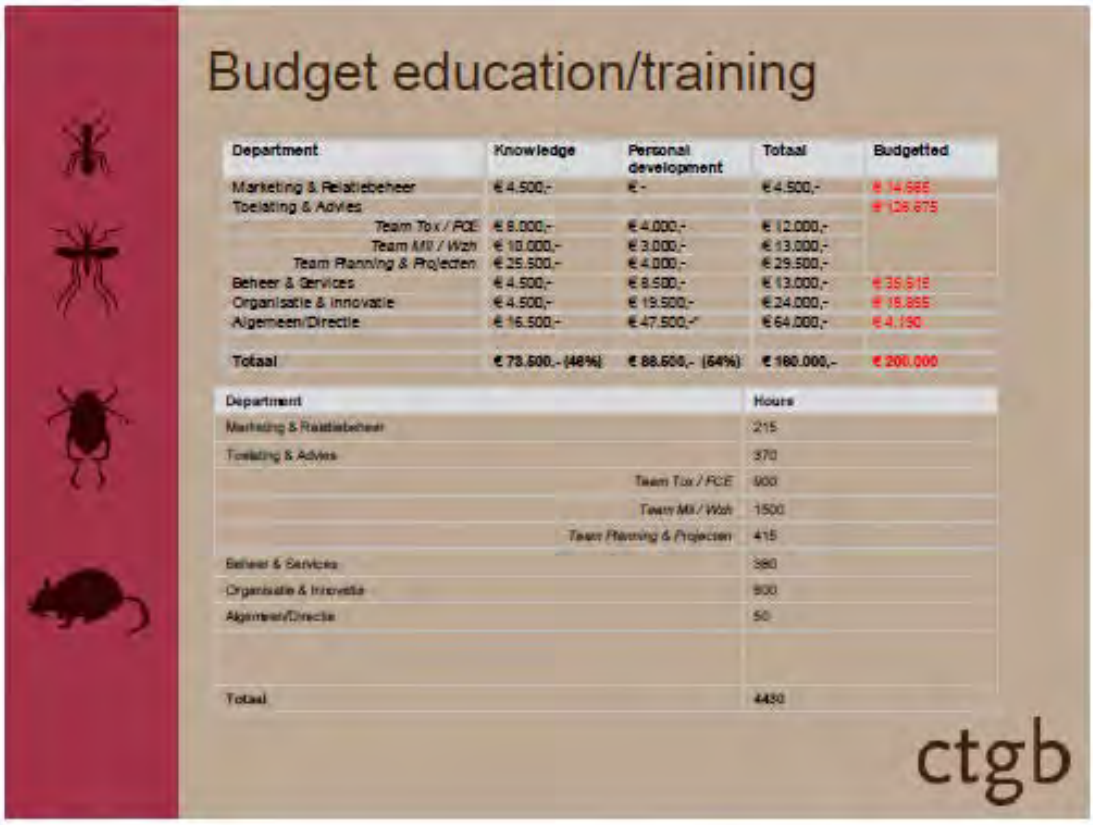

Recruitment & contracting proces
• Determine formation (how much and what expertise do we need?)
• Financial consequences
• Formative space
• Make recruitment plan (job description, ad text, job profile)
• Approve recruitment plan
• Selection process / selection committee / acquaintance committee
• Selection based on; knowledge, expertise, experience, skills, competencies)
• Job interview 1
• Job interview 2 + acq. committee
• Contracting
ctgb


Documents
ctgb


Introduction
• Introduction program (2 days)
• Initial (First) interview (manager/employee) (decide; knowledge, training, development, results, etc.)
• Evaluation interview (manager/employee) after 3-4 months (progress)
• Evaluation interview (manager/employee) once a year (progress, education, training, developing, competencies, etc.)
ctgb


Documents
ctgb


Education/training
Marketing & Customer relation management(4)
• BiSL game (functioneel beheer), New Biocidal Products Reg., Training Webcare, Word expert
T&A Tox/FCE (7)
• Epidemiology, DAPA meeting,Conferentie Mainz, Biopesticides, PET module Regulatory toxicology
T&A Mil/Wzh (18)
• Environmental Modelling Course, Geo PEARL, NBV seminar trends in environmental biotechnology, Mixture toxicity biocides, SETAC World, Congress Agchem forum, Excursion zomerbloementelers, SETAC Europe special science, Modelling Workshop, Demonstratie behandelingsmethode, Symposium Kennisnetwerk biociden, Bijeenkomst 'Samenwerken aan een schone Maas', Biopesticides, Workshop monitoring biocides, Legal & Reg
T&A Planning/projecten (7)
• Working group DRR format, Registration of agrochemicals in Europe, BPMS functioneel beheer, Planning & workflow system, BiSL game (functioneel beheer), Biopesticides, AgChem Forum
Management
• Veranderdiagnose en interventies (organisatie)
• Training Risicomanagement (MT)
ctgb



Budget education/training

Department	Knowledge	Personal development	Totaal	Budgetted
Marketing & Relatiebeheer	€ 4.500,-	€ -	€ 4.500,-	€ 14.665
Toelating & Advies				€ 126.675
Team Tox / PCE	€ 8.000,-	€ 4.000,-	€ 12.000,-	
Team Mil / Wzh	€ 10.000,-	€ 3.000,-	€ 13.000,-	
Team Planning & Projecten	€ 25.500,-	€ 4.000,-	€ 29.500,-	
Beheer & Services	€ 4.500,-	€ 8.500,-	€ 13.000,-	€ 35.915
Organisatie & innovatie	€ 4.500,-	€ 19.500,-	€ 24.000,-	€ 19.855
Algemeen/Directie	€ 16.500,-	€ 47.500,-"	€ 64.000,-	€ 4.190
Totaal	**€ 73.500,- (46%)**	**€ 88.500,- (54%)**	**€ 160.000,-**	€ 200.000

Department	Hours
Marketing & Relatiebeheer	215
Toelating & Advies	370
Team Tox / PCE	900
Team Mil / Wzh	1500
Team Planning & Projecten	415
Beheer & Services	380
Organisatie & Innovatie	900
Algemeen/Directie	50
Totaal	4430

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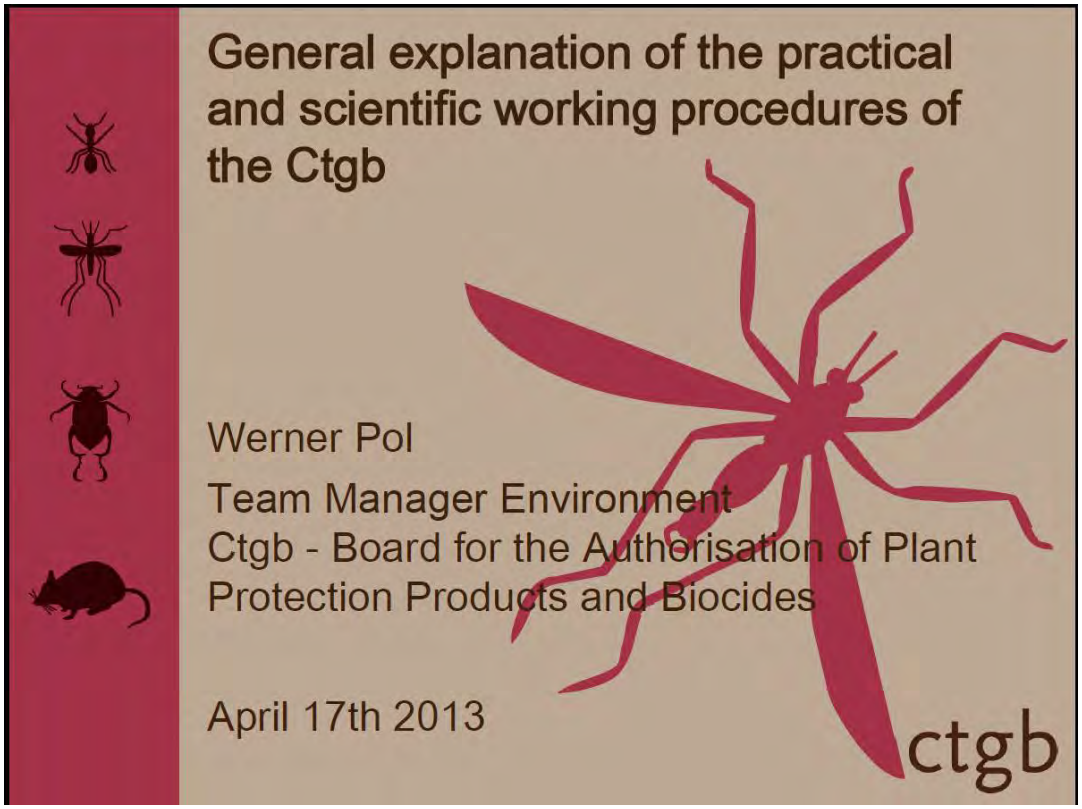
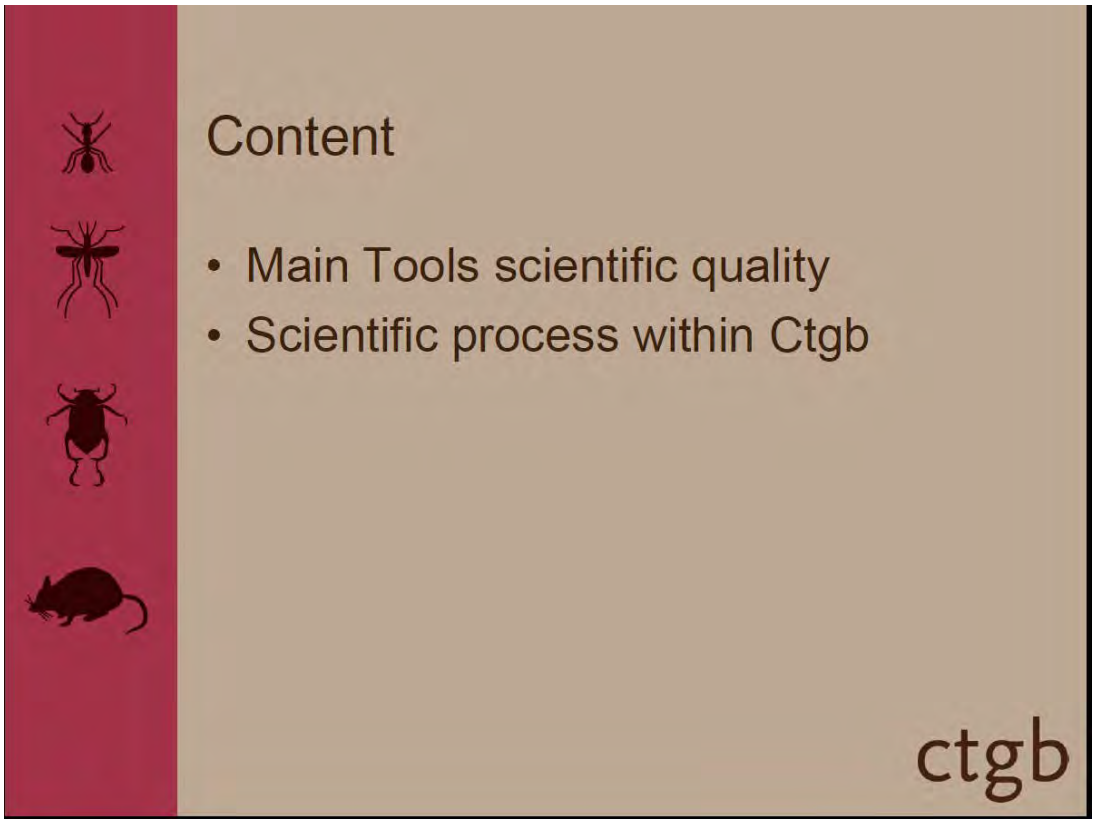
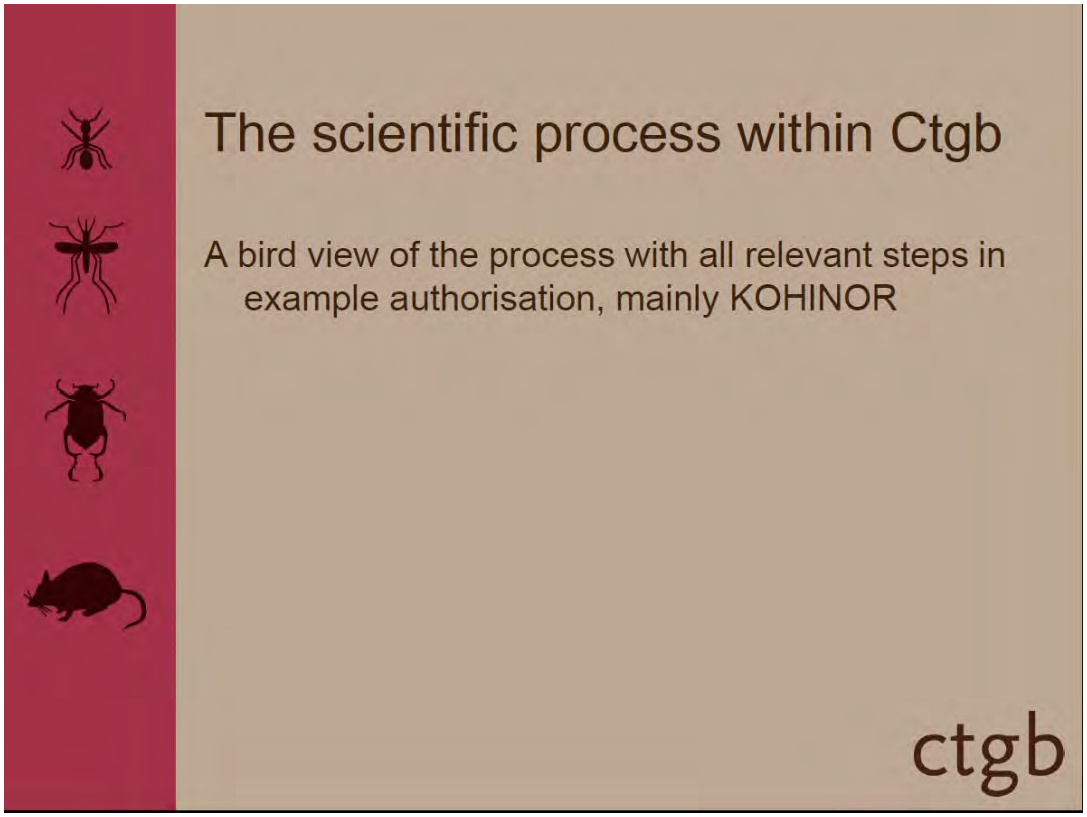
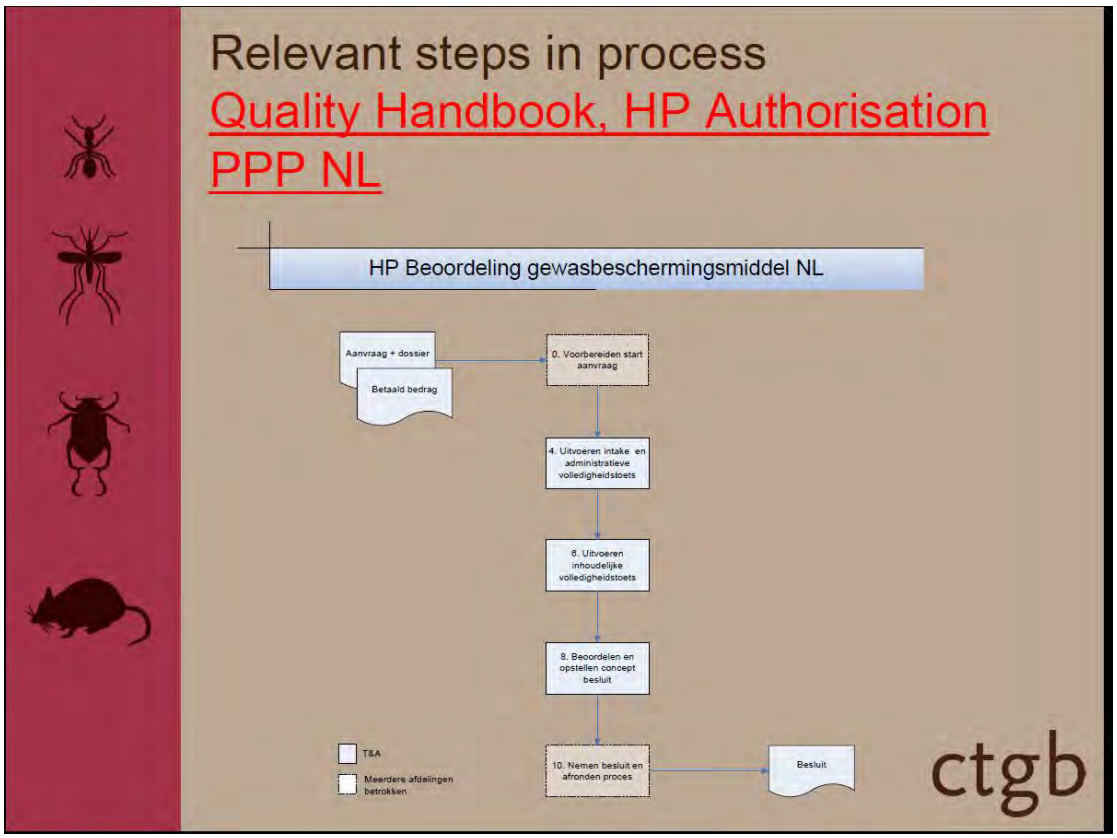
6 Second Presentation of Mr Werner Pol, Team Manager Environmental Assessment

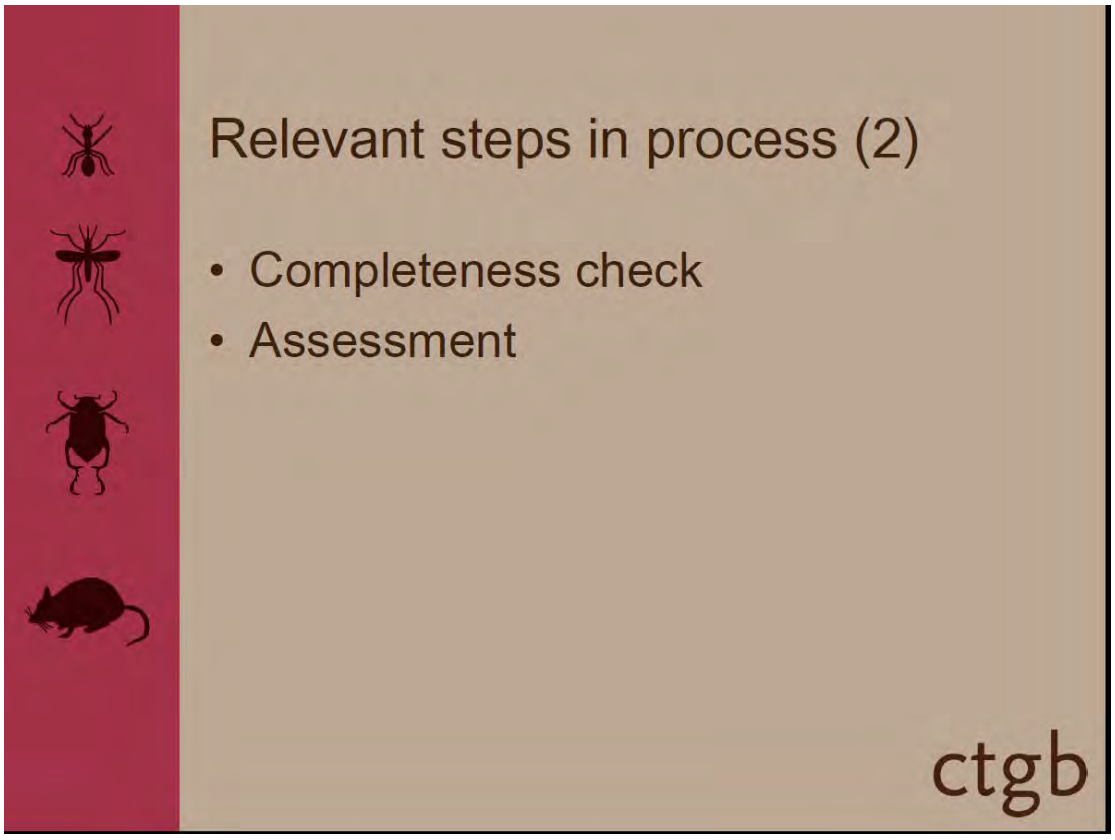





Scientific quality of authorisations
Main tools:
Assessment framework
– Implementation assessment framework (procedural)
Actual assessment framework PPP
– Implementation new GD/assessment methodology
⇒ Recording and Implementation in Evaluation Manual
Certiked
ISO 9001:2008
2009
Quality assessment
Quality Hand Book – Jobaids
Quality check assessments – Checklists
Evaluation Manuals for the Authorisations of PPP and biocides
Competence management
ctgb


The scientific process within Ctgb
A bird view of the process with all relevant steps in example authorisation, mainly KOHINOR
ctgb


Relevant steps in process
Quality Handbook, HP Authorisation PPP NL
HP Beoordeling gewasbeschermingsmiddel NL
Aanvraag + dossier
Betaald bedrag
0. Voorbereiden start aanvraag
4. Uitvoeren intake en administratieve volledigheidstoets
6. Uitvoeren inhoudelijke volledigheidstoets
8. Beoordelen en opstellen concept besluit
10. Nemen besluit en afronden proces
Besluit
T&A
Meerdere afdelingen betrokken
ctgb


Relevant steps in process (2)
• Completeness check
• Assessment
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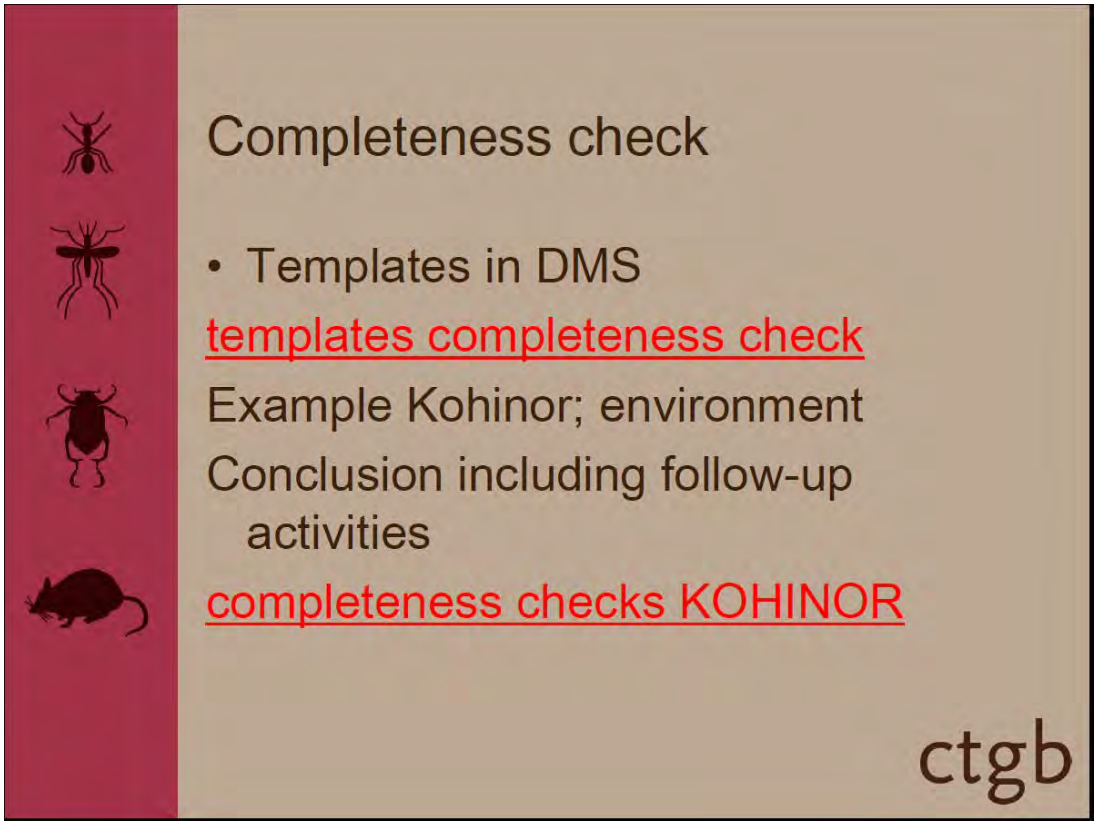
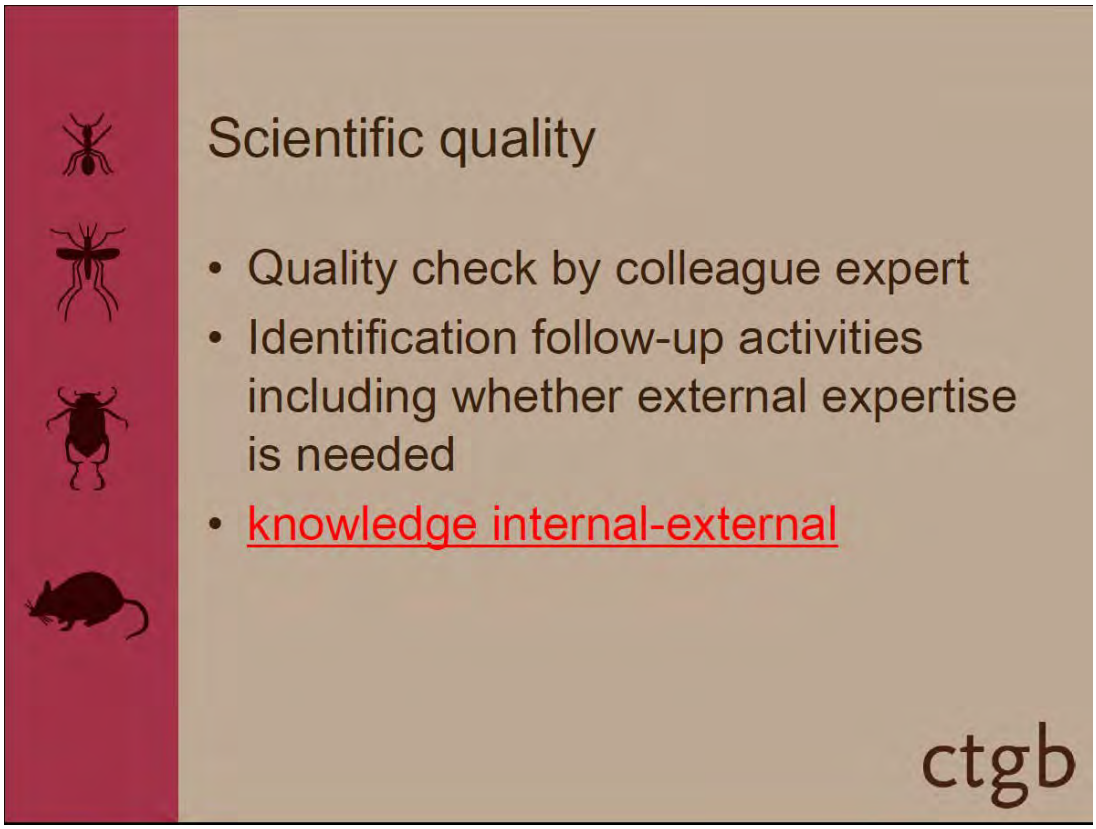
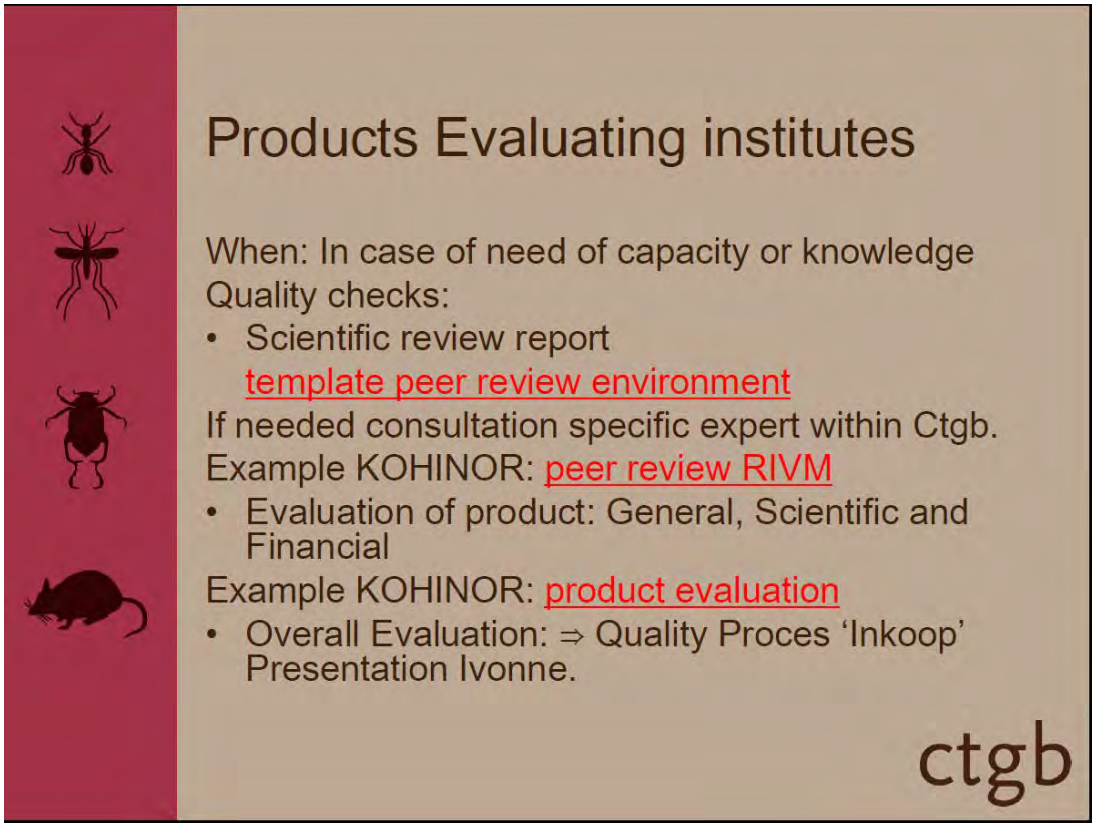
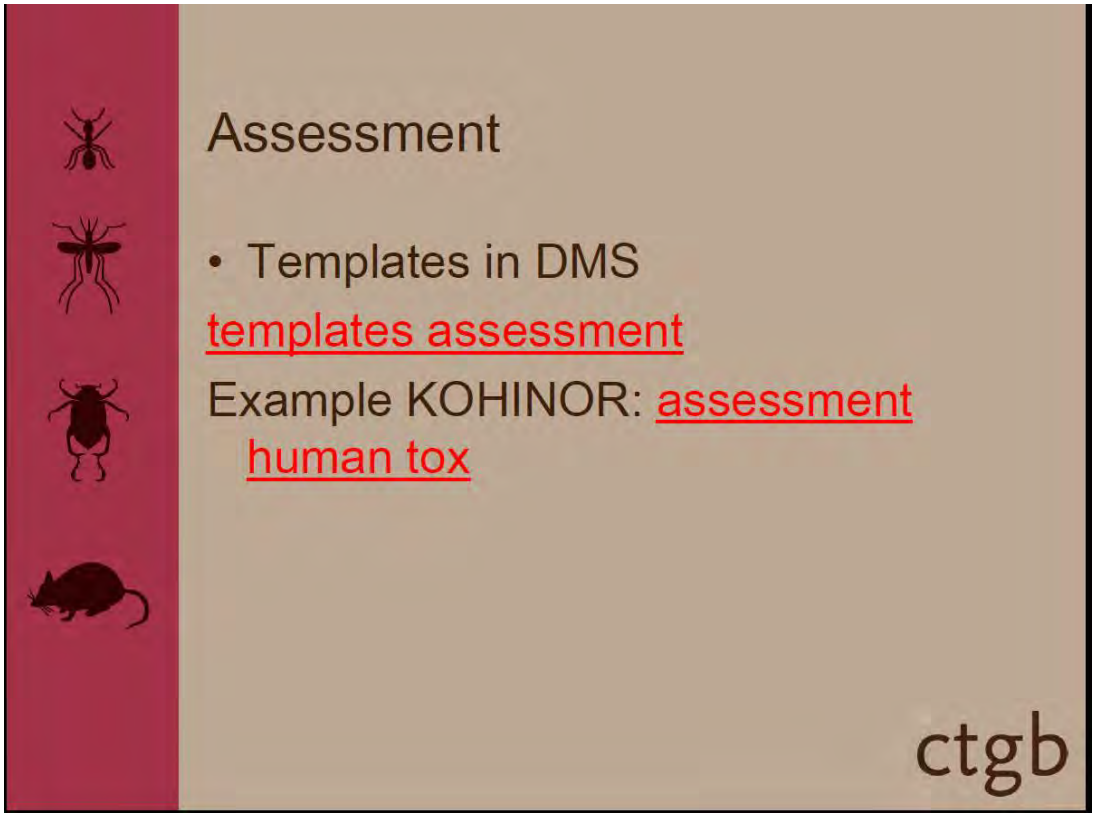
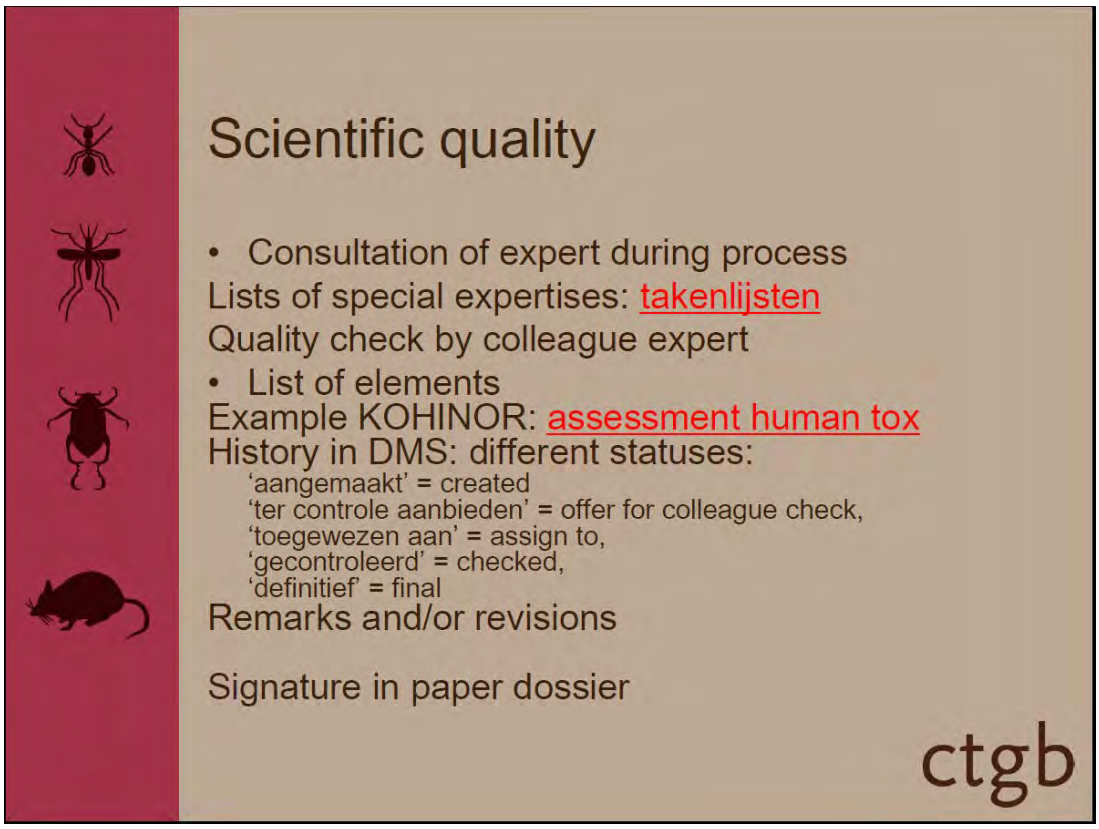
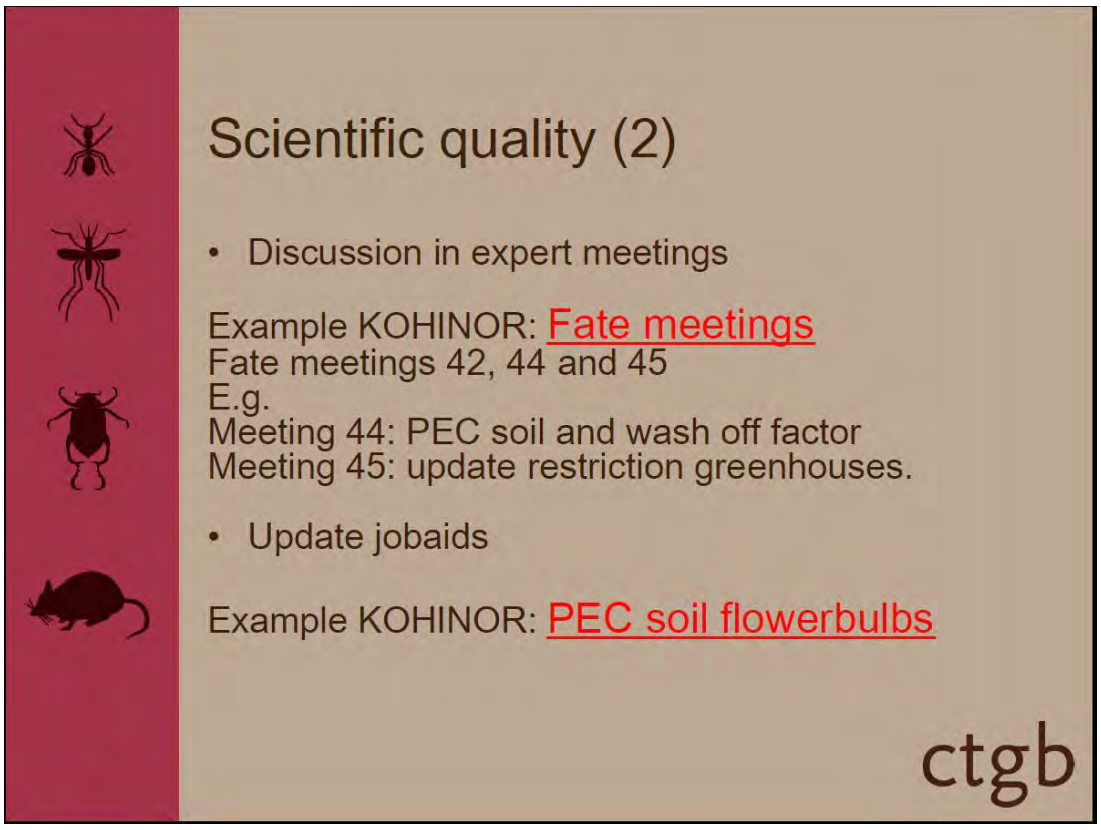

Completeness check
• Templates in DMS
templates completeness check
Example Kohinor; environment
Conclusion including follow-up activities
completeness checks KOHINOR
ctgb

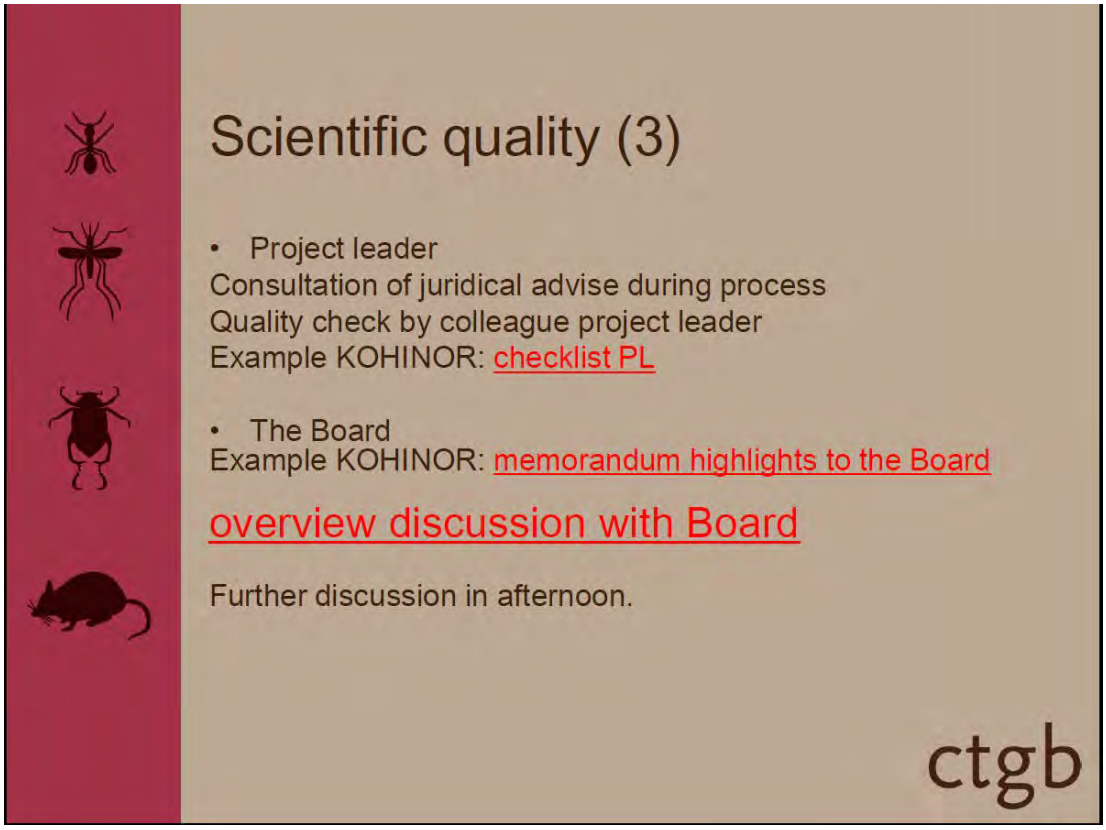

Scientific quality
• Quality check by colleague expert
• Identification follow-up activities including whether external expertise is needed
• knowledge internal-external
ctgb

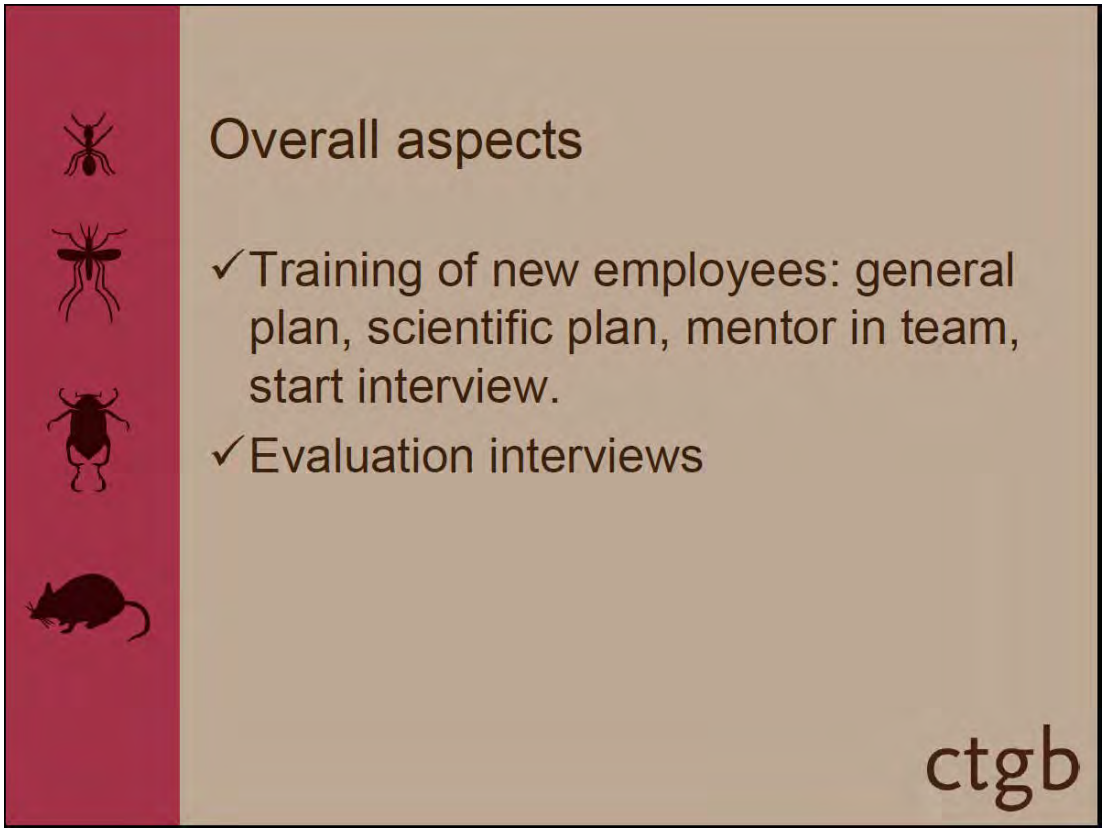

Products Evaluating institutes
When: In case of need of capacity or knowledge
Quality checks:
• Scientific review report
template peer review environment
If needed consultation specific expert within Ctgb.
Example KOHINOR: peer review RIVM
• Evaluation of product: General, Scientific and Financial
Example KOHINOR: product evaluation
• Overall Evaluation: ⇒ Quality Proces 'Inkoop' Presentation Ivonne.
ctgb

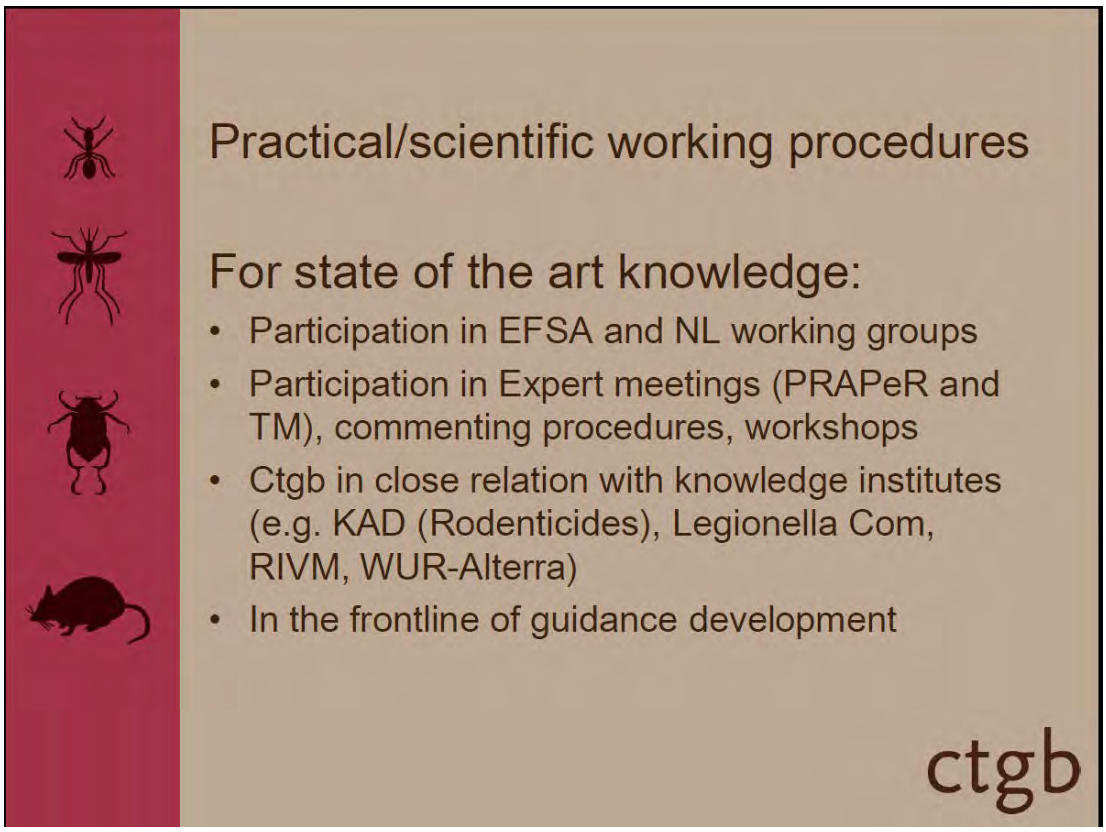

Assessment
• Templates in DMS
templates assessment
Example KOHINOR: assessment
human tox
ctgb

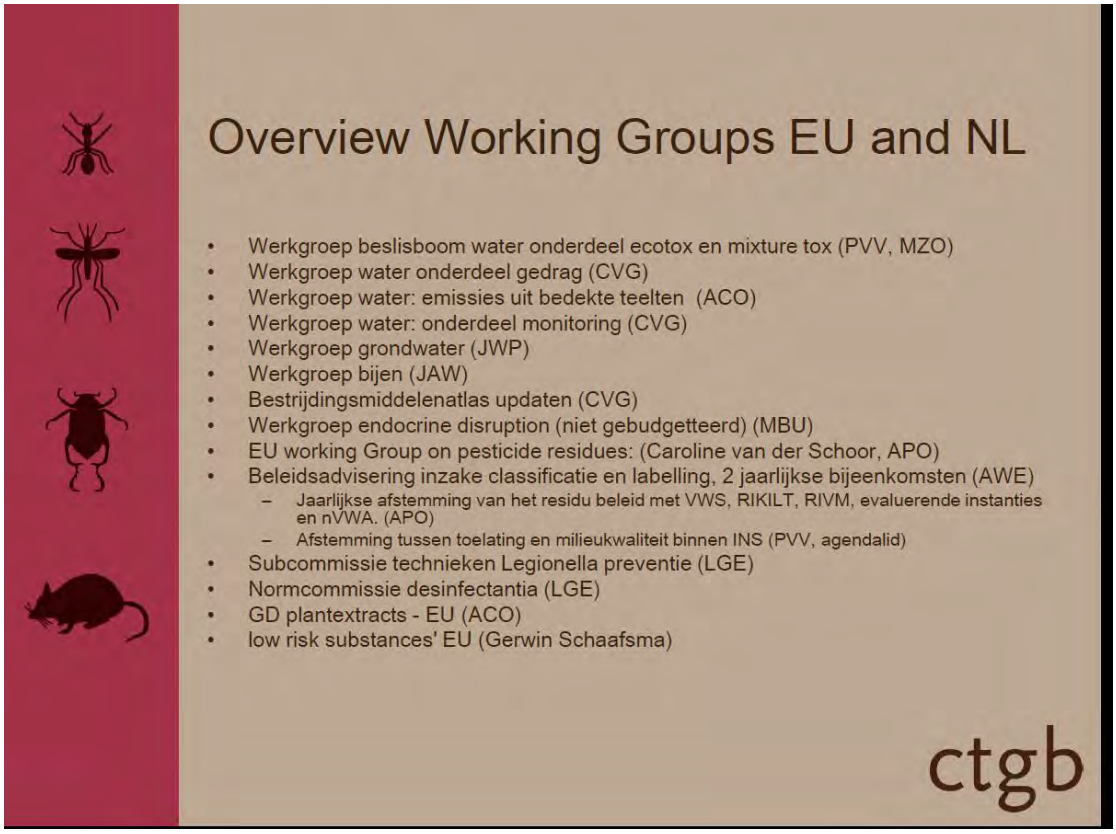

Scientific quality
• Consultation of expert during process
Lists of special expertises: takenlijsten
Quality check by colleague expert
• List of elements
Example KOHINOR: assessment human tox
History in DMS: different statuses:
'aangemaakt' = created
'ter controle aanbieden' = offer for colleague check,
'toegewezen aan' = assign to,
'gecontroleerd' = checked,
'definitief' = final
Remarks and/or revisions
Signature in paper dossier
ctgb


Scientific quality (2)
• Discussion in expert meetings
Example KOHINOR: Fate meetings
Fate meetings 42, 44 and 45
E.g.
Meeting 44: PEC soil and wash off factor
Meeting 45: update restriction greenhouses.
• Update jobaids
Example KOHINOR: PEC soil flowerbulbs
ctgb


Scientific quality (3)
• Project leader
Consultation of juridical advise during process
Quality check by colleague project leader
Example KOHINOR: checklist PL
• The Board
Example KOHINOR: memorandum highlights to the Board
overview discussion with Board
Further discussion in afternoon.
ctgb


Overall aspects
✓Training of new employees: general plan, scientific plan, mentor in team, start interview.
✓Evaluation interviews
ctgb


Practical/scientific working procedures
For state of the art knowledge:
• Participation in EFSA and NL working groups
• Participation in Expert meetings (PRAPeR and TM), commenting procedures, workshops
• Ctgb in close relation with knowledge institutes (e.g. KAD (Rodenticides), Legionella Com, RIVM, WUR-Alterra)
• In the frontline of guidance development
ctgb


Overview Working Groups EU and NL
• Werkgroep beslisboom water onderdeel ecotox en mixture tox (PVV, MZO)
• Werkgroep water onderdeel gedrag (CVG)
• Werkgroep water: emissies uit bedekte teelten (ACO)
• Werkgroep water: onderdeel monitoring (CVG)
• Werkgroep grondwater (JWP)
• Werkgroep bijen (JAW)
• Bestrijdingsmiddelenatlas updaten (CVG)
• Werkgroep endocrine disruption (niet gebudgetteerd) (MBU)
• EU working Group on pesticide residues: (Caroline van der Schoor, APO)
• Beleidsadvisering inzake classificatie en labelling, 2 jaarlijkse bijeenkomsten (AWE)
– Jaarlijkse afstemming van het residu beleid met VWS, RIKILT, RIVM, evaluerende instanties en nVWA. (APO)
– Afstemming tussen toelating en milieukwaliteit binnen INS (PVV, agendalid)
• Subcommissie technieken Legionella preventie (LGE)
• Normcommissie desinfectantia (LGE)
• GD plantextracts - EU (ACO)
• low risk substances' EU (Gerwin Schaafsma)
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Ctgb comments on evaluations other MS

- Chronologically comment tables
  Template: chronologically comments ecotox
  Examples: chronologically comments environment
- Comments in EU process in *italic* in assessment (LoEP)

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Questions?

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Discussions
• Publications of development of risk assessment methodologies
Peer reviewed journals –vs- reports
ctgb


More information at
http://www.ctgb.nl/
ctgb

Appendix 9

Primary Legislation Relevant to the Work of the Ctgb

Appendix 9: Primary Legislation Relevant to the Work of the Ctgb (Continued)

1 Dutch Legislative Measures

1.1 Wet Gewasbeschermingsmiddelen en Biociden, 17 October 2007 (Staatsblad 386, 2007) with the following additions: (i). Besluit aanvulling bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden, Ctgb, 2011 and (ii) Regeling houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden, 27 September 2007.

1.2 Warenwetregeling residuen van bestrijdingsmiddelen (Staatsblad 319, 1964), revised by decision of 23 April 1975 and on 31 January 1984

1.3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb, 31 oktober 2007

1.4 The Decree on the Mandate, Authorization and Representation by the Ctgb 2011, 3 March 2011, Government Gazette No 4789, 18 March 2011

1.5 Regulations for the Working Methods of the Board for the Authorisation of Plant Production Products and Biocides Decree. Board for the Authorization of Plant Protection Products and Biocides. Government Gazette, 7 December 2007, no. 238, page 12.

2 EU Legislation on Plant Protection Products

2.1 **Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market**. OJ No L230, 19.8.1991 p1

2.1.1 Commission Directive 93/71/EC of 27 July 1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 221, 31.8.1993, p27

2.1.2 Corrigendum to Commission Directive 93/71/EC of 27 July 1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No L4, 6.1.1996, p16

2.1.3 Commission Directive 94/37/EC of 22 July 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 194, 29.7.1994, p65

2.1.4 Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 354, 31.12.1994, p16

2.1.5 Corrigenda to Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 280, 23.11.1995, p58

2.1.6 Commission Directive 95/35/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 176, 22.7.1995, p6

2.1.7 Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 172, 22.7.1995, p8

2.1.8 Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms. OJ No L90, 8.4.2005 p1

2.1.9 Commission Directive 96/12/EC of 8 March 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 65, 15.3.1996, p20

2.1.10 Commission Directive 96/46/EC of 16 July 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 214, 23.8.1996, p18

2.1.11 Commission Directive 96/68/EC of 21 October 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 277, 30.10.1996, p25

2.1.12 Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No L265, 27.9.1997 p87

2.1.13 Commission Directive 2001/35/EC of 16 May 2001 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No 164, 20.6.2001, p1

2.1.14 Commission Directive 2003/82/EC of 11 September 2003 amending Directive 91/414/EEC as regards standard phrases for special risks and safety precaution for plant protection products. OJ No L228, 12.9.2003 p11

2.1.15 Commission Directive 2005/25/EC of 14 March 2005 amending Annex Vi to Directive 91/414/EEC as regards plant protection products containing micro-organisms. OJ No 90, 8.4.2005, p1

2.2 **Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/414/EEC**. OJ No L309 24.11.2009 p1

2.2.1 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ No 155, 11.6.2011, p1

2.2.2 Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products. OJ No 155, 11.6.2011, p67

2.2.3 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorization of plant protection products. OJ No 155, 11.6.2011, p127

2.2.4 Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products. OJ No 155, 11.6.2011, p176

2.2.5 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ No 93, 3.4.2013, p1

2.2.6 Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ No 93, 3.4.2013, p85

3 EU Legislation on Biocidal Products

3.1 **Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market**. OJ No L123, 24.4.1998, p1

3.1.1 Commission directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC concerning the placing of biocidal products on the market. OJ No L142, 30.5.2006, p6

3.1.2 Directive 2008/31 of the European Parliament and of the Council of 11 March 2008 amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission. OJ No L81, 20.34.2008, p57

3.2 **Regulation (EU No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.** OJ No L167, 27.6.2012, p1

3.2.1 Commission implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorized in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ No L109, 19.4.2013, p4

3.2.2 Commission implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorization of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ No L125, 7.5.2013, p4

Appendix 10

Guidance Documentation on Plant Protection and Biocidal Products

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

Part A: Guidance for use in the Evaluation of Plant Protection Products and their Active Substances to be used in preparing: -

- Draft Assessment Reports (DARs) for new active substances,
- Renewal Assessment Reports (RARs) for active substances already approved, and
- Registration Reports for the authorization or renewal of authorization of plant protection products

Note: The listing that follows in relation to Part A reflects the relevant content of the European Commission and OECD websites: -

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm

http://www.oecd.org/env/ehs/pesticides-biocides/

and

http://www.efsa.europa.eu/en/search.htm?text=guidance+documents&p=80

A-1 Commission Communications

- Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ No C95, 3.4.2013, p1

- Commission communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ No C95, 3.4.2013, p21

A-2 Guidelines for use in the assessment of the physical and chemical properties for the approval of active substances

- Guidance Document On Significant And Non-Significant Formulation Changes (104 KB) -November 2012
- The Working Document on microbial contaminant limits (420 KB) - September 2012
- Assessment of the Equivalence of Technical Materials of Substances (161 KB) - July 2012
- Finalisation of the reference specification for technical active substances after the peer review (32 KB) - July 2009
- Chemical substances - data requirements (152 KB) - doc 10473 - 6 July 2004
- CIPAC code numbers - July 2004
- Technical Material and Preparations - Analytical methods for Annex II (part A, Section 4) and Annex III (part A, Section 5) (47 KB) - 11 July 2000

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

A-3 Guidelines for use in the assessment of toxicity for the approval of active substances

- Acceptable operator exposure levels (160 KB) - 7531 rev 10 - 7 July 2006
- Dermal Absorption (198 KB) - 19 March 2004 - "Applicable from 1 December 2012/1 June 2013 depending on whether the guidance document does not trigger/triggers new studies to be submitted"
- Dermal absorption (256 KB) - 18 April 2012
- Acute reference dose (491 KB) - 7199/VI/99 -5 July 2001

A-4 Guidelines for use in the assessment of analytical methods for the approval of active substances

- Residues analytical methods - for post-registration control and monitoring (164 KB) - 17 March 2004
- Residues analytical methods - for pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) (76 KB) - 11 July 2000
- Method Validation and Quality Control procedures for Pesticide Residues SANCO/12495/2011 - implem. by 01/01/12 upd. 06/02/12
- Residue analytical methods - for post-registration control and enforcement SANCO/825/00 rev. 8.1, 16/11/2010 updated
- Residues analytical methods - for pre-registration data requirements under Directive 91/414 SANCO/3029/99 - 11 July 2000 updated
- Guidance provided by the EU Reference Laboratories for Pesticide Residues

A-5 Guidelines for use in the assessment of residues for the approval of active substances

- **Guidelines for residues data**
  - Foreword (7 KB) Doc. 1607/VI/97 - 10 June 1999
  - Appendix A - metabolism and distribution in plants (52 KB) Doc. 7028/VI/95 - 22 July 1997
  - Appendix B - general recommendations for the design, preparation and realization of residue trials (196 KB) Doc. 7029/VI/95 - 22 July 1997
  - Appendix C - testing of plant protection products in rotational crops (36 KB) Doc. 7524/VI/95 - 22 July 1997
  - Appendix D - comparability, extrapolation, group tolerances and data requirements (352 KB) Doc. 7525/VI/95 - 24 March 2011
  - Appendix E - processing studies (53 KB) Doc. 7035/VI/95 - 22 July 1997
  - Appendix F - metabolism and distribution in domestic animals (18 KB) Doc. 7030/VI/95 - 22 July 1997
  - Appendix G - livestock feeding studies (40 KB) Doc. 7031/VI/95 - 22 July 1996
  - Appendix H - storage stability of residue samples (23 KB) Doc. 7032/VI/95 - 22 July 1997
  - Appendix I - calculation of maximum residue levels and safety intervals (99 KB) Doc. 7039/VI/95 - 22 July 1997
- **OECD Maximum Residue Limit Calculator**
  - MRL Calculator Spreadsheet Single Data Set
  - MRL Calculator Spreadsheet Multiple Data Sets
  - User Guide
  - White Paper
- MRL application form (182 KB) Doc. 4044/2008 - 8 December 2008
- Template Evaluation Report 12 June 2009
- Working document guidance notes on "EC Import Tolerances" Doc. 7196/VI/99
- Notification criteria for pesticide residues SANCO/3346/01, rev 7 - 24 July 2004

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

A-6 Guidelines for use in the assessment of fate and behaviour for the approval of active substances

- The Working Document on environmental safety evaluation of MBCA (590 KB) - September 2012
- Assessment of the relevance of metabolites in groundwater (275 KB) - 25 February 2003
- FOCUS - Forum for the Co-ordination of pesticide fate models and their use
  - FOCUS Home page
  - Pesticides in Air: Considerations for exposure assessment, June 2008
  - Landscape and Mitigation factors in aquatic ecological risk assessment, September 2007
  - Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, June 2006
  - Groundwater scenarios in the EU review of active substances, January 2002
  - Soil persistence models and EU registration (600 KB), 29 February 1997
  - Surface water models and EU registration of plant protection products
  - Leaching models and EU registration (8 MB), June 1995
- Persistence in Soil (80 KB) - 9188/VI/97 - 12 July 2000

A-7 Guidelines for use in the assessment of ecotoxicity for the approval of active substances

- Risk assessment for birds and mammals: EFSA guidance document - EFSA Journal 2009; 7(12): 1438
- Risk assessment for birds and mammals: Joint working group report on the birds and mammals guidance document (101 KB) - 31 July 2009
- Aquatic Ecotoxicology (538 KB) - 17 October 2002
- Terrestrial Ecotoxicology (377 KB) - 17 October 2002
- Risk assessment for birds and mammals (835 KB) - 25 September 2002
- Ecotoxicology Database Report (0.1 Mb) Database extract (0.1 Mb) 18 December 2012

A-8 Guidelines for use in the assessment of crop specific issues for the approval of active substances

Assessment of active substances used on rice (7 MB) - June 2003

A-9 Procedural Guidelines for use in the preparation of Dossiers and Draft Assessment Reports

- Guidance document on preparing list of test and study reports; (51 KB)
- Guidance Document for applicants on preparing dossiers for the approval of a chemical active substance; (2 MB)
- Guidance Document on Rules for Revision of Assessment Reports; (464 KB)
- Template To Be Used For Assessment Reports (144 KB) - Word Version (205 KB) -November 2012
- Templates draft Registration Report for micro-organisms (464 KB) - September 2012
- Template for assessment reports - Level 3, Vol. 1, June 2012 (332 KB)
- Template for assessment reports - Level 3, Vol. 1, June 2012 (267 KB)
- Guidance on presenting and evaluating dossiers as per annex III, Directive 91/414/EEC as (draft) Registration Report - Annexes (doc. SANCO/6895/2009 rev 1) (2 MB) - 2 October 2009, updated January 2012
- Presenting and evaluating dossiers as per annex III (80 KB) - Oct. 2009
- Preparing and presenting complete dossiers for including active substances in Annex I (Article 5.3 and 8.2) (62 KB) - June 2005
- Preparing lists of studies (Annex I) - including existing active substances (2 MB) - April 2005

- Preparing dossiers and draft assessment reports for substances in the 4th stage of the review (Art. 8(2)) (189 KB) - Oct. 2004
- Plant extracts - data requirements (211 KB) - doc 10472 - July 2004
- Submitting dossiers for authorisation of plant protection products containing existing active substances after their inclusion in Annex I - Submission of an Annex II and Annex III Dossier (32 KB) - July 2000
- Submission of product dossiers (Risk Envelope Approach) (257 KB)
- Completeness check for new active substance dossier submissions (64 KB)
- Comparison list A (chemicals) - Annex II and Annex III points (OECD vs. former EC system) (142 KB)
- Comparison list B (microbials) - Annex II and Annex III points (OECD vs. former EC system) (66 KB)
- Completeness check evaluation forms
- Dossier submissions - instructions for industry (121 KB) - Dec. 2001
- Good Laboratory Practice - general requirements - 7017/VI/95 - June 1996
- Good Laboratory Practice - detailed requirements for Part A, Annexes II and III (34 KB) -7109/VI/94 - July 1995

A-10 OECD Guidance Documents for Chemical and Biological Registration

- **Dossier Guidance for industry - Chemical Plant Protection products**
  - pdf - Main document
  - pdf - Standard terms and abbreviations
  - pdf - Preparation (formulation) types and codes
  - pdf - Forms for use in reporting: 1. details of intended uses (GAP information); 2. registered uses and actual uses; 3. maximum residue limits (MRLs)
  - pdf - Format for compilation of Tier I quality checks
  - pdf - Forms for use in reporting: 1. crop residues data from individual supervised trials in summary form; 2. individual soil dissipation studies (soil residues) in summary form
  - Appendix 6 - Format for the listing of test and study reports and other documentation;
    - pdf 1. by test and study type, 2. by author, 3. of test and study reports and published papers not submitted
    - pdf - OECD, EU, US, Canadian, Japanese and Australian numbering systepdf ms for data and information on active substances
    - pdf - OECD, EU, US, Canadian, Japanese and Australian numbering systems for data and information on formulated product
  - Appendix 7 - Format for the compilation of Tier II summaries - active substance –
    - pdf - Indentity, Physical and chemical properties, further information, proposals including justification of the proposals for the classification and labelling of the active substance
    - pdf - Analytical methods
      - pdf - Toxicological and metabolism studies on the active substance
      - pdf - Residues in or on treated products, food and feed
      - pdf - Fate and behaviour in the environment
    - Appendix 8 - Format for the compilation of Tier II summaries - formulated product –
      - pdf - Identity, Physical, chemical and technical properties, Data on application, Further information, Proposals including justification of the proposals for the classification and labelling of the plant protection product
      - pdf - Toxicological Studies and Exposure Data and Information
      - pdf - Ecotoxicological Studies and risk assessment
      - pdf - Efficacy Data and Information
  - pdf - Format for the listing of endpoints to be included in the Tier III overall summary and assessment
  - pdf - Format for the compilation of Tier III overall summaries and assessments
  - pdf - Forms for use in checking dossiers for completeness
- **Dossier Guidance for industry - Microbial Plant Protection products**
  - Microbials Dossier Main Document

- Appendix 1
- Appendix 2
- Appendix 3
- Appendix 4
- Appendix 5
- Appendix 6a Parts 1,2,3
- Appendix 6b Part 4
- Appendix 6c Part 5
- Appendix 7
- Appendix 8
- Appendix 9
- Appendix 10
- Appendix 11

- **Dossier Guidance for industry- Pheromones and Semiochemicals**
  - Pheremone Dossier Main Document
    - Appendix 1
    - Appendix 2
    - Appendix 3
    - Appendix 4
    - Appendix 5
    - Appendix 6 Parts 1,2,3
    - Appendix 6 Part 4
    - Appendix 6 Part 5
    - Appendix 7
    - Appendix 8
    - Appendix 9
    - Appendix 10
    - Appendix 11 Part 1
    - Appendix 11 Part 2
    - Appendix 11 Part 3
    - Appendix 11 Part 4
    - Appendix 11 Part 5
- **Monograph Guidance for Governments –Chemical Plant protection Products**
  - pdf - Main document
  - pdf - Standard terms and abbreviations
  - pdf - Preparation (formulation) types and codes
  - pdf - Guidance with respect to pagination, lay-out, tables and references
  - pdf - Suggested order for the preparation of each of the four levels and three annexes of the monographs to be prepared by regulatory authorities
  - pdf - Form for use in reporting details of intended uses (GAP information)
  - pdf - Format for the listing of end points to be included in the reasoned statement of the overall conclusions drawn by the regulatory authority (Level 2)
  - pdf - Format for the listing of test and study reports and other documentation evaluated (Annex A)
  - pdf - Format for the listing of test and study reports and other documentation relied on (Annex B)
  - pdf - Guidance Notes for Analysis and Evaluation of Particular Types of Studies
- **Monograph Guidance for Governments –Microbial**
  - Microbials Guidance Main document
    - Appendix 1
    - Appendix 2
    - Appendix 3
    - Appendix 4
    - Appendix 5
    - Appendix 6
    - Appendix 7
    - Appendix 8

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

- **Monograph Guidance for Governments –Pheromones and Semiochemicals**
  - Pheremones Monograph Main Document
    - Appendix 1
    - Appendix 2
    - Appendix 3
    - Appendix 4
    - Appendix 5
    - Appendix 6
    - Appendix 7
    - Appendix 8
    - Appendix 9

A-11 OECD Guidance on Work Sharing and Joint Reviews

- Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides
  Series on Pesticides **No. 60** ENV/JM/MONO(2011)11
- Frequently Asked Questions about Work Sharing on Pesticide Registration Reviews
  Series on Pesticides **No. 34** ENV/JM/MONO(2007)1
- Overview of Country and Regional Review Procedures for Agricultural Pesticides and Relevant Documents.
  Series on Pesticides **No. 33** ENV/JM/MONO(2006)38

A-12 Guidance on Post Approval Issues

- Working document on emergency authorisations according to Article 53 (236 KB)
- Renewal Guidance on implementation of Regulation (EU) No 844/2012 (133 KB) - July 2012
- Evaluation of new active substance data post approval (22 KB) - 24 January 2012
- Zonal Evaluation and Mutual Recognition (347 KB)
- Renewal, Withdrawal and Amendment of Authorisations (161 KB)
- Assessment of new isolates of baculovirus species already included in Annex I (122 KB)
- Assessment of new Straight Chain Lepidopteran Pheromones (SCLPs) (66 KB)
- Authorization of plant protection products following inclusion of an existing active substance (58 KB) - 15 July 2011
- Authorization of Plant Protection Products containing existing active substances after their inclusion in Annex I - Submission of an Annex II & Annex III dossiers (200 KB)
- Intra & inter-zonal work-sharing to facilitate the registration and re-registration (49 KB)- 2 October 2009
- Mutual Recognition (39 KB)- 2 December 2008
- Guidance document concerning the parallel trade of plant protection products - SANCO/10524/2012 (336 KB) - 31 May 2012
- Renewal Guidance on implementation of Regulation (EU) No 1141/2010 (58 KB) - 28 October 2010
- Submission and assessment of confirmatory data (53 KB)- July 2011
- Voluntary mutual recognition of minor use authorizations (336 KB) - 10 October 2000

A-13 Guidance on Procedural Issues

- Guidance Document on data Protection (169 KB)
- Borderline concerning Biocidial products and Plant Protection Products - Biocides/26/99 - 30 April 2001
- Formatting of Draft Evaluation Reports (2 MB) - 1654/VI/94 - 22 April 1998

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

- Guideline developed within the Standing Committee on the Food Chain and Animal Health on the taxonomic level of micro-organisms to be included in Annex I (37 KB) - 15 April 2005, Updated 14-12-2006
- Preparation of Review Report for review Stage 2 substances and new active substances considered by EFSA (175 KB) - 15 April 2005

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

Part B: Guidance for use in the Evaluation of Biocidal Products and their Active Substances to be used in preparing: -

- Competent Authority Reports (CARs) for active substances, and
- Registration Reports for the authorization or renewal of authorization of biocidal products

Note: The listing that follows in relation to Part B reflects the relevant content of the European Commission and OECD websites -

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd/technical-guidance-document-tgd

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/euses/euses

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/evaluation-process

http://www.oecd.org/env/ehs/pesticides-biocides/biocidepublications.htm

and

http://www.oecd.org/env/ehs/risk-assessment/theoecdqsartoolbox.htm#Download_qsar_application_toolbox

B-1 Technical Notes on Data Requirements

- TNsG on Data Requirements document provides guidance on the data requirements and waiving arguments that are required for biocidal active substances and products.
- Addenda are available for: -
  - Rodenticides (PT 14),
  - Insecticides (PT 18), oils and extracts (PT 19),
  - Naturally occurring substances (PT 19),
  - Pheromones (PT 19),
  - Micro-organisms including viruses and fungi,
  - Analytical methods.

B-2 Technical Notes on Annex I Inclusion

- TNsG on Annex I Inclusion document identifies criteria for unacceptable/acceptable effects and associated conditions for inclusion of active substances onto Annex I (or IA or IB). A revised Chapter 10 on "Resistance" and a revised Chapter 4.1 on "Quantitative Human Health Risk Characterization" are available.

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

B-3 Technical Notes on Product Evaluation

- TNsG on Product Evaluation document provides guidance on how to perform the administrative and scientific evaluation of applications for authorisation and registration. A revised appendix to chapter 7 on efficacy of rodenticides and a revised Chapter 6.2 on resistance, both from 2009, are available.

B-4 Technical Notes on Human Exposure

- TNsG on Human Exposure document (2007 *) provides guidance on the estimation of Human Exposure to biocidal products for all Product Types.

  The first version of this TNsG is from 2000. This 2000 version was revised two times.
  The most recent version is of 2008 (which includes an Excel file containing default exposure data for all PTs). An addendum on how to obtain BEAT including a password and a corrigendum for PT 21 are available.
  NEW An earlier version is available: 2002 (Technical Notes for Guidance - Human Exposure to Biocidal Products - Guidance on Exposure Estimation - In four parts: Foreword and summary - Part 1 - Part 2 - Part 3), as well as User Guidance - Version 1 - Human Exposure to Biocidal Products (TNsG June 2002).
  A Guidance on the use of the human exposure guidance for the Review Programme and the peer-review of new active substances (2009) is also available.
  In 2007 the Human Exposure Expert Group (HEEG) was established. This group discusses issues that arise during discussions on active substances during the evaluation process, as well as issues on methodology and needs for update of guidance documents: Opinions of the HEEG endorsed by the TM.

  A workshop on Human Exposure to Biocides took place in Oslo on 24-26 February 2009, including three sessions: health and safety during the use of biocidal products, occupational exposure assessment for biocidal products using BEAT, consumer exposure assessment for biocidal products using ConsExpo. See also the Training material.

B-5 Technical Notes on Dossier Preparation and Study Evaluation

The TNsG on Dossier Preparation and Study Evaluation guidance focuses primarily on applications for the inclusion of active substances onto Annex I (or IA or IB). It is intended to give guidance on how the documentation to be submitted by the applicant should be prepared and presented. The TNsG is available in 3 parts as:

- Part I
- Part II
- Part III - NEW also available in Word format: Part III (1; 2; 3; 4; 5; 6)

The following additional information is available:

- Application codes for PT 08, PT 14, PT 18, 19 e 20;
- Standardised tables to present the risk characterisation for human health.

B-6 Technical Notes on the Dossier Preparation and Study Evaluation

- TNsG on the assessment of technical equivalence guidance is intended to establish harmonised criteria and processes for assessing the equivalence of different sources of a substance versus the reference source.

B-7 Working Procedures

- **Standard Operating Procedure (SOP) [fourth version, June 2012]**

- Manual of Technical Agreements (MOTA) (Version 4, September 2011)

B-8 Additional Guidance on Specific Issues

- Guidance on the relevance of the manufacturing process when carrying out the risk assessment under the BPD;
- Guidance on the product dossier for Annex I inclusion of an active substance;
- Guidance on how to treat degradation and sorption data for groundwater assessment;
- Guidance on rapidly degrading substances;
- Guidance on the use of a plant protection products monograph and existing substances risk assessment reports under the BPD;
- Guidance on risk characterisation of local effects in the absence of systemic effects;
- Guidance on the relevance of REACH guidance for dossier evaluation under the BPD;
- Guidance on leaching rate estimation for PT 07, 09 and 10;
- Guidance on the role of efficacy in the evaluation of active substances for Annex I inclusion.

B-9 Technical Guidance Document (TGD)

The EU TGD for risk assessment of new and existing substances and biocides is the basis for risk assessment of active substances.

- **Part I General Introduction & Risk Assessment for Human Health**
  - tgdpart1_2ed.pdf 7.0 MB
  - tgdpart1_2ed.zip 3.6 MB
- **Part II Environmental Risk Assessment**
  - tgdpart2_2ed.pdf 6.5 MB
  - tgdpart2_2ed.zip 3.0 MB
- **Part III Use of (Quantitative) Structure Activity Relationships ((Q)SARs), Use Categories, Risk Assessment Report Format**
  - tgdpart3_2ed.pdf 2.1 MB
  - tgdpart3_2ed.zip 988.1 kB
- **Part IV Emission Scenario Documents**
  - tgdpart4_2ed.pdf 8.5 MB
  - tgdpart4_2ed.zip 3.7 MB

B-10 Emission Scenario Documents (ESDs)

- **Workshop Environmental RA PT 01-06 2008**
  - PT1-6_Cover_Note_Workshop_Environment_Risk_Assessment_2008.pdf
  - PT1-6_Workshop_Environmental_Risk_Assessment_2008.pdf
- **Training Course Materials**
  - ESD_Introduction_PvdZ.ppt — PowerPoint presentation, 6455Kb
  - ESD_Rodenticides_JL.ppt — PowerPoint presentation, 286Kb
  - ESD_Wood_preservatives_BH.ppt — PowerPoint presentation, 717Kb

  PT8 Wood preservatives
  - PT8_Exercise_Answers.doc — Microsoft Word Document, 96Kb
  - PT8_Exercise_A_Results.xls — Excel spreadsheet, 144Kb
  - PT8_Exercise_B_Results.xls — Excel spreadsheet, 145Kb
  - PT8_Exercise_Questions.doc — Microsoft Word Document, 78Kb

- PT8_Version1_2.xls — Excel spreadsheet, 155Kb

PT14 Rodenticides

- Excercise_1.doc — Microsoft Word Document, 63Kb
- Excercise_1_including_answers.doc — Microsoft Word Document, 39Kb
- Excercise_2.doc — Microsoft Word Document, 123Kb
- Excercise_2_including_answers.doc — Microsoft Word Document, 99Kb
- Excercise_3.doc — Microsoft Word Document, 98Kb
- Excercise_3_including_answers.doc — Microsoft Word Document, 73Kb
- Excercise_4.doc — Microsoft Word Document, 115Kb
- Excercise_4_including_answers.doc — Microsoft Word Document, 90Kb
- PT14_calculation_spreadsheet.xls — Excel spreadsheet, 148Kb
- PT14_calculation_spreadsheet_including_answers.xls — Excel spreadsheet, 148Kb

ESD Product Type

- PT_1_Human_Hygiene.pdf — PDF document, 529Kb
- PT_2_Private_area_and_public_health_area_disinfectants.pdf — PDF document, 233Kb
- pt2.pdf — PDF document, 756Kb
- pt3.pdf — PDF document, 967Kb
- pt4.pdf — PDF document, 667Kb
- PT_5_Drinking_water_disinfectants.pdf — PDF document, 877Kb
- PT_6_In-Can_preservatives.pdf — PDF document, 290Kb
- PT_6_PT_7_PT_9_Paper_coating_and_finishing.pdf — PDF document, 170Kb
- PT_7_Film_preservatives.pdf — PDF document, 342Kb
- OECD_Guidance_Emission_Estimation_Treated_Wood_2009.pdf — PDF document, 308Kb
- PT_8_ground_water_assessment.pdf — PDF document, 23Kb
- PT_8_Leaching_Workshop_2005.pdf — PDF document, 1162Kb
- PT_8_Wood_preservatives_1.pdf — PDF document, 349Kb
- PT_8_Wood_preservatives_2.pdf — PDF document, 321Kb
- PT_8_Wood_preservatives_3.pdf — PDF document, 337Kb
- PT_8_Wood_preservatives_4.pdf — PDF document, 254Kb
- PT_9_Leather_industry.pdf — PDF document, 138Kb
- PT_9_PT_18_Textile_processing_industry.pdf — PDF document, 164Kb
- PT_9_Rubber_Polymerised_Materials_preservatives.pdf — PDF document, 442Kb
- PT_10_Masonry_preservatives.pdf — PDF document, 341Kb
- PT_11_Preservatives_for_liquid-cooling_and_processing_systems.pdf — PDF document, 1015Kb
- PT_12_Slimicides.pdf — PDF document, 868Kb
- PT_13_Metalworking_fluid.pdf — PDF document, 355Kb
- Addendum-TGD-PNEC_Derivation_Rodenticides.pdf — PDF document, 27Kb
- PT_14_Rodenticides.pdf — PDF document, 319Kb
- PT_15_Avicides.pdf — PDF document, 329Kb
- OECD_ESD_PT18_Household_Professional_Uses.pdf — PDF document, 3297Kb
- PT18_Workshop_Environmental_Risk_Assessment_2007.pdf — PDF document, 127Kb
- PT_18_Insecticides_for_stables_and_manure.pdf — PDF document, 496Kb
- PT_9_PT_18_Textile_processing_industry.pdf — PDF document, 164Kb
- PT_21_antifouling_products.pdf — PDF document, 1221Kb
- PT_21_Leaching_Workshop.pdf — PDF document, 112Kb
- MAMPEC-V2-User-Manual-and-Short-Guide-final.pdf — PDF document, 789Kb
- REMA-erratum.pdf — PDF document, 466Kb

- REMA-users-guide.pdf — PDF document, 2452Kb
- REMA_Software.zip — Zip archive, 8908Kb
- Outcome e-consultation Germany environmetal risk assessment 2011.zip — Zip archive, 33Kb
- PT_22_Embalming_and_taxidermist_fluids.pdf — PDF document, 112Kb
- PT_22_Embalming_and_taxidermist_fluids.pdf — PDF document, 597Kb

- **ESD Overview**
  - ESDs_Detailed_overview.doc — Microsoft Word Document, 146Kb
  - ESDs_Short_overview_with_links.doc — Microsoft Word Document, 73Kb
- **Additional Information**
  - ESDs_INFU_20000.pdf — PDF document, 852Kb
  - ESDs_RIVM_2000_Proposals_for_Symbols.pdf — PDF document, 182Kb
  - ESDs_RIVM_2001_ESD_PT1-PT23.pdf — PDF document, 1756Kb

B-11 European Union System for the Evaluation of Substances (EUSES)

- Chapter 3, "Model Calculations"
- EUSES User Manual 2.1
- NEW EUSES 2.1.2 Release Notes

Blacklist documents containing an overview of inconsistencies or errors which became apparent after EUSES 2.1 was released:

- NEW EUSES 2.1.2 blacklist (general)
- EUSES blacklist (specific for biocides)

The EUSES version 2.1.2 is based only on blacklist items; there is no separate functional or technical design or scientific model document. All items that were put on the blacklist document are processed built, fixed or solved. The program can be downloaded (free of charge) here:

- NEW EUSES 2.1.2 Installation
  (updated 19 January 2012) The zipped file includes: executable program Euses21.exe; calculation library Ceus21.dll; online help file Euses21.hlp; support files

Training material on EUSES in general and the application of EUSES for the evaluation of biocides is available:

- Introduction to EUSES
- Introduction to EUSES-Biocides
- 19 presentations from a course held in May 2009

B-12 Guidance Documents

Biocides - Borderline with plant protection products.pdf	93.42 KB	27 September 2012 09:16	
Biocides - Guidance note on data protection.pdf	149.48 KB	27 September 2012 09:16	
Biocides - Teat dips.pdf	84.07 KB	27 September 2012 09:16	
Biocides-2002-01 - Borderline with (veterinary) medicinal products.pdf	24.78 KB	27 September 2012 09:16	
Biocides-2002-03-rev1 - Borderline with cosmetic	156.35 KB	27 September	

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

products.pdf		2012 09:16
Biocides-2002-04-Rev3 - Scope issues.pdf	95.94 KB	27 September 2012 09:16
Biocides-2002-06-Rev2 - Scope issues.pdf	169.79 KB	27 September 2012 09:16
CA-Dec05-Doc.8.2 - Data requirements for microorganisms.doc	354.5 KB	10 June 2008 09:01
CA-Dec09-Doc.8.3 - Note on multiple dossiers.doc	94.5 KB	12 February 2010 15:42
CA-Dec09-Doc.8.4 - Comparative assessment.doc	61 KB	26 September 2012 14:18
CA-Dec12-Doc.6.2.a - Final _TNsG_efficacy_PT18-19.doc	849.5 KB	9 January 2013 17:10
CA-Dec12-Doc.6.2.b -final - Evaluation _Manual_version_1.0.doc	1.75 MB	18 December 2012 13:25
CA-Dec12-Doc.6.2.c - final -CAR template.doc	254.5 KB	18 December 2012 14:02
CA-Dec12-Doc.6.2.d - final - SOP_notifications_Art4(4).doc	102 KB	18 December 2012 14:06
CA-Feb11-Doc.6.1.a - Notes for Guidance on frame formulations.doc	131 KB	6 June 2011 17:34
CA-Feb13-Doc.5.1.1 - Final - Substances in Annex I of the BPR.doc	308 KB	18 March 2013 17:05
CA-Feb13-Doc.5.2.b -Final - Anticoagulant rodenticides renewal.doc	76.5 KB	12 March 2013 11:07
CA-July11-Doc.6.2a - LoA final for publication.doc	62 KB	31 August 2011 19:10
CA-July12-Doc.6.2.d - Relevance of new guidance.doc	51.5 KB	20 July 2012 11:47
CA-July12-Doc.8.4 Final - Late withdrawal of applicant.doc	64 KB	20 July 2012 12:04
CA-June07-Doc.6.1.3 - Completeness checks - final.doc	47.5 KB	10 June 2008 09:02
CA-March07-Doc.6.3 - Risk Mitigation Measures Anticoagulants - final.doc	65.5 KB	10 June 2008 09:03
CA-March07-Doc.9.1.2 - Template for active substances assessment report.doc	316 KB	26 September 2012 14:18
CA-March12-Doc.7.2 final - BPD application in EEZs.doc	92 KB	11 May 2012 14:21
CA-May08-Doc.11.1.1 - PA&MRFG Mandate and Rules of procedure final.doc	71.5 KB	26 September 2012 14:18
CA-May08-Doc.6.2 - Use of PPE.doc	63.5 KB	10 June 2008 09:23
CA-May08-Doc.6.7 - TNsG Technical Equivalence.doc	197.5 KB	10 June 2008 09:04
CA-May11-Doc.6.2b Final - Note on C and L.doc	64.5 KB	26 September 2012 14:18
CA-May12-Doc.11.6 Final post CA - Mutual recognition of anticoagulants.doc	71 KB	5 June 2012 08:38

CA-May12-Doc.6.2a Final post CA - Active substances generated in situ.doc	126.5 KB	5 June 2012 08:38	
CA-May12-Doc.6.2b Final post CA - Use of published data.doc	95 KB	5 June 2012 08:38	
CA-Nov06-Doc.9.2 - Level of detail of annex I inclusion.doc	60.5 KB	26 September 2012 14:18	
CA-Nov07-Doc.10.2 - Chromium.doc	88 KB	26 September 2012 14:18	
CA-Nov07-Doc.3.0 - Background note on Annex I inclusions.doc	84.5 KB	26 September 2012 14:18	
CA-Nov07-Doc.3.2.2 - Inclusion in Annexes IA and I.doc	66.5 KB	26 September 2012 14:18	
CA-Nov07-Doc.6.1 - SOP on development of guidance documents.doc	78 KB	26 September 2012 14:18	
CA-Nov07-Doc.6.4 - Scientific Committees Referral.doc	74.5 KB	26 September 2012 14:18	
CA-Sept06 - Additional_Guidance_Product_Dossier_for_Annex_I_Inclusion .pdf	13.75 KB	26 September 2012 14:18	
CA-Sept06-Doc.6.1.2 - Clarification paper on QUATS (BKC and DDAC).doc	92.5 KB	26 September 2012 14:18	
CA-Sept07-Doc.5.3 - Spraying method for amateur users.doc	61 KB	26 September 2012 14:18	
CA-Sept08-Doc.12.1 - Interlinkage REACH Biocides.doc	115.5 KB	26 September 2012 14:40	
CA-Sept09-Doc.3.4a - MRLs.doc	877 KB	26 September 2012 14:18	
CA-Sept10-Doc.8.7 - Substance redefinition final.doc	57 KB	16 September 2011 15:18	
CA-Sept11-Doc.6.3b Final General policy note CAR publication.doc	68.5 KB	1 December 2011 22:13	
CA-Sept12-Doc.6.2.a - Notes for guidance for applicants for PA&MR_rev2.doc	969.5 KB	28 January 2013 15:29	
CA-Sept12-Doc.6.2.b - Note for guidance to MSs compliance check PA.doc	106.5 KB	27 September 2012 15:53	
PA&MRFG-May11-Doc.4 - Post-annex I inclusion procedure - final.doc	590.5 KB	10 May 2011 10:46	

B-12 OECD Guidance Documentation

- Series on Testing and Assessment No. 183 and Series on Biocides No. 5: Guidance Document on Assays for Testing the Efficacy of Baits against Coackroaches
- Series on Testing and Assessment No. 170 and Series on Biocides No. 4: Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants and Field Testing
- OECD Series on Testing and Assessment, No. 107: This document is intended to provide guidance to applicants wishing to have particular active substances approved or wood preservative products registered in OECD countries. It provides guidance with respect to the collection, preparation, quality,

and reporting of emission data to be submitted to enable an environmental risk assessment of emissions of wood preservatives from treated wood to be performed.

- OECD Guidelines for the Testing of Chemicals Test No. 313: Estimations of Emissions from Preservative - Treated Wood to the Environment, for wood not covered and in contact with fresh water or sea water (*for emissions from wood or wooded commodities that are not covered, permanently exposed to wetting and are in contact with the ground, governments may wish to consider the approach described in OECD Guideline No. 313, AWMA or other approaches for generating data*)
  ENV/JM/MONO(2008)27
  Series on Biocides No. 1
  Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects

B-13 OECD Emission Scenario Documentation

- Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Uses (June 2008)
  Series on Emission Scenario Documents No. 18
  ENV/JM/MONO(2008)14
- Emission Scenario Document for Insecticides for stable and manure storage (January 2006)
  Series on Emission Scenario Documents No. 14:
  ENV/JM/MONO(2006)4
- Emission Scenario Document on Antifouling Products (April 2005)
  Series on Emission Scenario Documents No. 13:
  ENV/JM/MONO(2005)8 and ANNEX
- Emission Scenario Document for Wood Preservatives (February 2003)
  Series on Emission Scenario Documents No. 2:
  PART 1
  PART 2
  PART 3
  PART 4
  [produced jointly with the Task Force on Environmental Exposure Assessment (TFEEA). For other ESDs produced by the TFEEA, see this site]

B-14 OECD QSAR Toolbox Guidance Document sand Training Materials

Download the QSAR Toolbox (v3.1) (560 MB) Stand Alone or Server-Client Version
Download What's new in TB 3.0
Download the Release Notes 3.0 Release Notes 3.1
Download the Installation instructions: • Stand Alone installation • Server-Client installation and configuration
Download the Toolbox 3.0 Database migration
Download the Manual for getting started
Download the Quick reference guidance for getting started

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

Note:
- Due to the size of the files, the downloads may take a few minutes.
- The same download facilities are also available on the following mirror web sites:

Laboratory of Mathematical Chemistry
www.qsartoolbox.org

The manuals of the QSAR Toolbox can be downloaded from the following table:

Title	Link, document number/version and date of publication
IUCLID 5 Import/Export via Webservices	PDF (1.1; February 2011)
Guidance document for using the OECD (Q)SAR Application Toolbox to develop chemical categories according to the OECD Guidance on Grouping of Chemicals*	Series on Testing and Assessment No. 102 (2009)
Guidance on importing databases	PDF (1.0; April 2011)
Tips and tricks	PDF (1.1; February 2011)
Strategies for grouping chemicals for data gap filling for acute aquatic toxicity endpoints*	PDF (2010)
Strategies for grouping chemicals to fill data gaps to assess genetic toxicity and genotoxic carcinogenicity	PDF (1.0; January 2011)

* NOTE: These guidance documents were written for version 1.1. They will be updated over the coming months.

Training materials for the Toolbox are also available below. This material can be freely used for training purposes.

Title and main features	Slides	Video tutorial
Step-by-step example on how to predict the skin sensitisation potential approach of a chemical by read-across based on an analogue approach (for beginners)	pdf	Video
Step-by-step example of how to predict aquatic toxicity for an untested target chemical by the trend analysis approach (for beginners)	pdf	
Step-by-step example of how to predict Ames mutagenicity for a chemical by a qualitative read-across approach. (for beginners)	pdf	
Step-by-step example of how to predict acute toxicity to Tetrahymena pyriformis by trend analysis using category pruning capabilities (December 2012)	pdf	Video
Step-by-step example of how to build and evaluate a category based on mechanism of action with protein and DNA binding (December 2012)	pdf	Video

Appendix 10: Guidance Documentation on Plant Protection and Biocidal Products (Continued)

Step-by-step example of how to build a category for more than one target chemicals and predict acute toxicity to fish (December 2012)	pdf	
Step-by-step example of how to evaluate an ad-hoc category of aliphatic amines and to predict an ecotoxicological endpoint (December 2012)	pdf	
Step-by-step example of how to build a user-defined profiling scheme (December 2012)	pdf	Video
Step-by-step example of how to categorize an inventory by mechanistic behaviour of the chemicals which it consists (December 2012)	pdf	
Step-by-step example of how to build a user-defined QSAR (December 2012)	pdf	Video

Additional training material will be published as it is developed.

The OECD does not foresee to organise training sesions for the use of the Toolbox. Nevertheless training sessions are organised by other organisations which are referenced here:

- International (Q)SAR Foundation
- Laboratory of Mathematical Chemistry

Appendix 11

Education, Training and Experience of Ctgb Scientific Staff

Appendix 11: Education, Training and Experience of Ctgb Scientific Staff (Continued)

Number of staff/members	Education and highest diploma level	Years of work experience [1] prior to Ctgb (average)	Years at Ctgb (average)	On the job training while at Ctgb	Publications (average)
The Board [2]					
8	PhD: 5 MSc or equivalent: 3	31.4	2.6	Not applicable	75 [3]
Senior Management					
5	PhD: 2 MSc or equivalent: 1 BSc: 2	17.4	5.6 [4]	Not applicable	Not indicated
Department of Authorization and Advisory Services (74 Scientific Staff Members)					
Team Managers					
4	PhD: 1 ERT [5]:1 MSc or equivalent: 3	7.4 [6]	10.3 [7]	9.5 [8]	7.8
Project Coordinators					
23 [9]	PhD: 8 ERT: 1 MSc or equivalent: 11 BSc: 3 Undergraduate: 1	5.7 [10]	5.0 [11]	1.4 [12]	2.9
Scientific Assessors - Human Toxicology					
10	PhD: 5 ERT: 5 MSc or equivalent: 5	3.6	4.6 [13]	3.3	11.1
Scientific Assessors - Consumer Safety (Residues)					
4	PhD: 2	7.5	2.7	3.3 [14]	1.8 [15]

Appendix 11: Education, Training and Experience of Ctgb Scientific Staff (Continued)

Number of staff/members	Education and highest diploma level	Years of work experience [1] prior to Ctgb (average)	Years at Ctgb (average)	On the job training while at Ctgb	Publications (average)
	MSc or equivalent: 2				
Scientific Assessors - Environment and Fate					
20 [16]	PhD: 9 MSc or equivalent: 10 BSc: 1	8.2	4.4 [17]	3.9 [18]	6.0
Scientific Assessors - Efficacy Biocides and Pesticide Products					
9	PhD: 4 MSc or equivalent: 5	14.6	2.1 [19]	1.7	16.7 [20]
Scientific Assessors - Chemistry and Analytical Methods					
4	MSc or equivalent: 3 BSc: 1	4.0 [21]	3.5 [22]	2.0	0
Department of Marketing & Customer Relations Management					
7	PhD: 4 ERT: 2 MSc or equivalent: 3	11.7 [23]	11.4	4.4	9.3 [24]
Department of Organization & Innovation					
6	PhD: 1 MSc or equivalent: 5	8.8	4.2	3.0	3.3 [25]

Note to the table: percentages are based on 74 staff members directly involved in the scientific work and exclude senior management, and staff of the departments of 'marketing & customer relation' and of 'organization and innovation':

- Education: 39% PhD; 53% MSc; 7% BSc; 1% Undergraduate. 7 staff members (<10%) are recognized as ERT.
- 33% of the staff involved in the scientific work have participated in international regulatory assessment work related to PPPs and/or biocides
- 25% of the staff involved in the scientific work have published at least 1 paper in peer reviewed scientific journals

- 22% of the staff involved in the scientific work have been invited at least once to give a scientific presentation on PPP/Biocide assessment in another country than The Netherlands
- 41% of the staff involved in the scientific work participated at least once in training/refresher courses or similar events while at the Ctgb

[1] As paid work

[2] There is one vacancy

[3] Two members did not provide information; number of publications ranged from 7-165.

[4] Three senior managers are 1 year or less at Ctgb, one is 6 and one is 19 years at Ctgb.

[5] ERT = European Registered Toxicologist (PhD equivalent)

[6] Ranging from 0-24

[7] Ranging from < 1-16 years

[8] One of the team managers listed 30+ training events

[9] Five staff members did not provide the IVC with their resume other than their highest education degree

[10] Ranging from 0-18 years

[11] Six project coordinators are < 1 year in Ctgb

[12] One project coordinator listed 10 training events and one listed 5, all others listed 0-2

[13] Five assessors are 1 year or less in Ctgb

[14] One assessor listed 12 training events, the others none

[15] One assessor listed 7 publications, the others none

[16] Two staff members did not provide the IVC with their resume other than their highest education degree

[17] Five assessors are 1 year or less in Ctgb

[18] One assessor listed 32 training events

[19] Four assessors are 1 year or less in Ctgb

[20] One assessor listed 94 and another listed 34 publications

[21] One assessor listed 11 years of work experience prior to Ctgb

[22] Two assessors are < 1 year with Ctgb

[23] One staff member did not provide information about work experience prior to Ctgb

[24] Five staff members reported none or not relevant publications

[25] One staff member listed 19 publications, 4 listed none