

The background is a painting of a landscape. The upper portion is dominated by a vibrant blue sky filled with soft, white, and light blue clouds. Below the sky, there is a dark, horizontal band that appears to be a distant shoreline or a row of trees. The foreground is filled with tall, golden-yellow grasses, rendered with visible brushstrokes, giving it a textured, painterly appearance.

*Report of the second
visitation of the Netherlands
Board for the Authorization of
Plant Protection Products
and Biocides (Ctgb)*

*addressing the scientific process,
the scientific output and the
decision-making process*



I N M E M O R I A M

Mark Lynch

1943 - 2018

Soon after starting its work in January 2018 the IVC was confronted with a sad loss, when the IVC member Mark Lynch suddenly and unexpectedly passed away. Mark was a person with an excellent level of expertise, experience and kindness, and his loss strongly affected the work of the IVC. We are fortunate to have had an opportunity to work with him. We all miss him tremendously and we convey our deepest condolences to his wife Maura and family.

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09/2018

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Executive Summary

At the request of the Board for the Authorisation of Plant Products and Biocides (Ctgb), which is the Competent Authority in the Netherlands, a second international evaluation was made of the scientific processes used by the Ctgb and of the scientific quality of its decisions and other technical output in the first half of 2018, some 5 years after an initial similar scrutiny. The recent evaluation focussed not only on the same issues, thus allowing comparison with the 2013 visitation, but it also focussed on progress with respect to outreach and the role of the Ctgb in the EU. Furthermore, attention was given to the role of the Board, its relationship with the scientific staff and with the human resources management.

Based on the experience gained during the 2013 evaluation, the appointed International Visitation Committee in 2018 adopted a similar approach that was endorsed by the Board. The IVC relied exclusively on information made available by Ctgb together with relevant documentation on the websites of the European Commission and its agencies and other international organisations. Ctgb provided access to a considerable number of documents, the vast majority of which were considered to be highly confidential. This information was augmented by interviews with Ctgb staff and Board members.

The IVC examined the structure and management of Ctgb, the academic qualifications and experience of its staff and the human resources policy, the openness and transparency throughout the organisation, the scientific processes and scientific output, the documentation of its decisions, mechanisms to keep up to date with international scientific developments, and legal issues and support. Additional insight was provided by Ctgb on the 7 recommendations (out of 29) made in 2013 which had not been accepted and implemented.

Largely general and some specific recommendations were drawn from the observations made by the IVC for consideration by the Ctgb addressing the topics evaluated: (i) the Board and (human resource) management (ii), openness and transparency, and (iii) scientific outputs and outreach. The IVC recognises the considerable progress made throughout the organisation since 2013, with the large increase in qualified and experienced staff, the high scientific quality attained, an efficient management system and in general sound implemented internal processes

compliant with international requirements. No instance was found by the IVC in which either a Ctgb risk assessment or a risk management decision was considered to be inadequately grounded or to be inappropriate. Nevertheless, the IVC is unanimous in its opinion that Ctgb should be more open and transparent as a common theme running throughout the organisation. This would better help to distinguish between the fundamentally important risk assessment and subsequent risk management decisions. It would also enhance communication with peers and the wider society, enhance recognition of its excellent staff capability and could result in gaining greater public trust.

The overall conclusion of the IVC is that the Ctgb is a strong, science-driven regulatory agency with a clear commitment to reduce the risks of pesticides to human health and the environment. The Ctgb is well run, the skilled staff and management of the Ctgb are collegial in their approach, and the work atmosphere within the agency, as experienced by the IVC, was very pleasant.

Samenvatting

Op verzoek van het College voor de toelating van gewasbeschermende middelen en biociden (Ctgb), de bevoegde autoriteit in Nederland, werd van januari tot augustus 2018 een tweede internationale evaluatie uitgevoerd van de wetenschappelijke processen van het Ctgb, van de wetenschappelijke kwaliteit van de besluiten van het College, en van andere wetenschappelijke en technische documenten en publicaties. Deze visitatie is ongeveer 5 jaar na een eerste vergelijkbaar onderzoek uitgevoerd. De recente evaluatie richtte zich niet alleen op dezelfde aspecten, waardoor vergelijking met de visitatie van 2013 mogelijk was, maar richtte zich ook op de vooruitgang met betrekking tot de reikwijdte en de rol van het Ctgb in de EU. Verder werd aandacht besteed aan de rol van het College, de relatie van het College met de wetenschappelijke staf en de relatie met het personeelsmanagement.

Op basis van de ervaring opgedaan tijdens de evaluatie van 2013, heeft de door het College aangestelde Internationale Visitatiecommissie (IVC) in 2018 een vergelijkbare aanpak voorgesteld, die door het College werd goedgekeurd. De IVC heeft zich met name gericht op informatie die door het Ctgb ter beschikking werd gesteld, en daarnaast ook op relevante documentatie op de websites van de Europese Commissie en haar agentschappen en andere internationale organisaties. Het Ctgb heeft de IVC toegang gegeven tot een aanzienlijk aantal documenten, waarvan de overgrote meerderheid als zeer betrouwbaar werd beschouwd. Deze informatie werd aangevuld met interviews met Ctgb-medewerkers en leden van het College.

De IVC heeft de structuur en het management van het Ctgb geëvalueerd, alsmede de academische kwalificaties en ervaring van de staf, het personeelsbeleid, de openheid en transparantie in de gehele organisatie, de wetenschappelijke processen en wetenschappelijke output, de documentatie van de door het College genomen besluiten, de wijze waarop het Ctgb bij blijft met betrekking tot internationale wetenschappelijke ontwikkelingen, en hoe juridische kwesties worden ondersteund. Het Ctgb heeft ook verdere toelichting gegeven op het besluit om 7 van de 29 aanbevelingen die in 2013 werden gedaan niet te aanvaarden en implementeren.

Het IVC heeft voornamelijk algemene en enkele specifieke aanbevelingen gedaan, gebaseerd op haar waarnemingen en heeft deze ter overweging aan het College aangeboden.

De aanbevelingen zijn gegroepeerd in drie clusters, te weten: (i) het College en (personeels-) management; (ii) openheid en transparantie; en (iii) wetenschappelijke resultaten en reikwijdte.

De IVC erkent de aanzienlijke vooruitgang die de gehele organisatie sinds 2013 heeft geboekt; met de grote toename van gekwalificeerd en ervaren personeel, de hoge wetenschappelijke kwaliteit die is bereikt, een efficiënt managementsysteem en over het algemeen goed uitgevoerde interne processen die voldoen aan internationale vereisten. De IVC heeft geen enkel geval gevonden waarbij een risicobeoordeling dan wel een risicomanagementbeslissing van de Ctgb onvoldoende onderbouwd werd geacht of als onjuist werd beoordeeld.

Niettemin is de IVC unaniem van mening dat het Ctgb meer open en transparant zou moeten zijn. Dit is een kenmerkend thema door de hele organisatie heen. Transparantie zou helpen om beter onderscheid te maken tussen de fundamenteel belangrijke risicobeoordeling en de daaropvolgende risicomanagementbeslissingen. Het zou ook de communicatie met collega-wetenschappers en de samenleving in het algemeen verbeteren, de erkenning van de uitstekende kwaliteiten en capaciteiten van de staf vergroten, en zou kunnen resulteren in een groter publiek vertrouwen in de Ctgb.

De algemene conclusie van de IVC is dat het Ctgb een sterke, wetenschappelijk gedreven regelgevende autoriteit is, met een sterke betrokkenheid om de risico's van plant protectie producten en biociden voor de menselijke gezondheid en het milieu te verminderen. Het Ctgb wordt adequaat bestuurd, de vakkundige medewerkers en het management van het Ctgb zijn collegiaal in hun aanpak, en de werksfeer binnen de organisatie, zoals ervaren door de IVC, is goed.

Introduction

In 2013, at the request of the Chairman of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) an international visitation committee made a thorough evaluation of the scientific processes used by the Ctgb and of the scientific quality of the decisions and other technical output of the organisation. The report of this evaluation (IVC Report of the international visitation of the Ctgb, July 2013) concluded that “there were no instances in which either a risk assessment prepared, or a risk management decision made was considered to be inadequately grounded or inappropriate”. Nonetheless, in its report the International Visitation Committee offered some 30 recommendations for further improvement.

In November 2017 the Chairman of the Ctgb Board requested the Chair of the 2013 International Visitation Committee (Dr Herman Koëter, Scientific Director of the European Food Safety Authority from its establishment until November 2008), to organize and carry out a follow up, similar international evaluation in the first half of 2018.

Ctgb

The Ctgb is an independent and impartial agency that acts as an intermediary between the general public, society, industry, politicians, farmers and producers, pest management professionals and infection control specialists, all of whom need to be able to rely on and trust the Ctgb. As an independent authority, the Ctgb is responsible for the national implementation of the Plant Protection Products and Biocidal Products Act. The activities of the Ctgb are overseen by the Ministry of Agriculture, Nature and Food Quality (plant protection products) and the Ministry of Infrastructure and Water Management (biocidal products). Furthermore, the Ministry of Health, Welfare and Sport and the Ministry of Social Affairs and Employment are involved with topics related to their policy areas.

The international Visitation Committee (IVC)

It was agreed that the IVC 2018 would comprise no more than 4 members plus the Chairman, preferably from 5 EU member states. The Terms of Reference were signed on 22nd November 2017 (Annex 1), subject to the approval of the Board and to the availability of appropriate experts to serve on the committee. The Terms of Reference require that the IVC 2018 addresses in particular:

- a) the scientific quality and legal compliance of decisions made regarding the authorisation of plant protection and biocidal products, and
- b) dealing with all stakeholders (including the European Commission, regulatory authorities in EU member states, NGOs and the general public).

Members of the IVC 2018 were identified and selected by the Chair as potential candidates on the basis of the following criteria:

- a) 20+ years of experience in life sciences in the public sector and/or as independent consultant,
- b) Recognised expertise in active substance and product evaluation and approval of biocides and/or plant protection products in the EU,
- c) Able to spend substantial time in this project between January and September 2018, including some travelling to the Ctgb offices
- d) As a group: balanced in relation to expertise in both plant protection and biocide risk assessment and management considering the range of scientific disciplines involved.

By letter of 29 November 2017, the proposed membership of the IVC 2018 was confirmed by the Board of the Ctgb. The members of the IVC 2018 who were formally appointed by the Board and whose CVs are provided in Annex 2, were:

- Dr Sari Autio, Finland.
- Dr Mar Carretero, Spain (as of 17 April)
- Prof. Anthony Hardy, United Kingdom
- Dr Herman Koëter, Italy (Chairman)
- Dr Mark R Lynch, Ireland. (Until 27 March)
- Dr Alberto Mantovani, Italy

Sari Autio, Herman Koëter, and Mark Lynch had also been members of the IVC Committee in 2013.

Approach

Much to the dismay of all members of the IVC 2018, Dr Mark Lynch passed away just a few weeks after the second meeting of the IVC meeting. Mark's sudden death was first and foremost a great loss for his family. Being the most experienced and knowledgeable member of the IVC 2018, finding within a few weeks a successor with a similar profile and of the same quality and availability has proven to be a great challenge. Nonetheless, the truncated IVC membership managed to propose a new member that would fit well in the team. On 17 April, Dr Mar Carretero from Spain was confirmed by the Board as the new 5th member of the IVC 2018.

Prior to commencing their work, the members of the IVC 2018 signed Declarations of Interest with regard to their assignment as members of the IVC 2018 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 Annexes 3 and 4.

Action Plan

Based on the experience gained during the first visitation in 2013 the members of IVC 2018 decided to propose to the Board a similar approach as used in 2013, being as follows:

- starting with the collection of data and information from documents, scientific reports, minutes of meetings, communication notes and internet searches
- planning Board and other staff interviews
- assessing and evaluating all relevant information gathered
- drafting a compilation of any recommendations
- providing the draft report of the visitation to the Board for scrutinization of the report for misunderstandings and errors
- presenting the final report to the Board.

The Draft Action Plan also contained an outline of the approach of the IVC 2018 for evaluating the scientific process, the scientific output and the decision-making processes of the Board. It included a list of quality indicators for each of the three focus areas (32 indicators in total). In addition, 4 indicators of efficiency and transparency and, as appropriate, 4 indicators of success in fostering sustainable pest management were proposed. The Draft Action Plan and time schedule was submitted for comments and suggestions to the Board and Senior Management of the Ctgb in the first week of February. On 20th of February the slightly amended Action Plan was accepted and signed. The Action Plan is attached as Annex 5.

Meetings

In conducting its work, the IVC met in face-to-face meetings on:

1. 17 January: Preliminary introductory meeting on action plan suggestions, strategy, tasks and timing. Venue: Orange House Partnership office in Brussels, Belgium.
2. 28 February: introduction, meeting with the Board, approval of the Activity Plan and introduction to the 'Document Management System (DMS). Venue: Ctgb offices, Ede, the Netherlands
3. 24 April: Introduction of a new IVC member (Mar Carretero from Spain) replacing Mark Lynch after his sudden and unexpected death. Assignment of tasks, selection of dossiers, furthering acquaintance with the DMS: venue Ctgb offices, Ede, The Netherlands
4. 23-24 May: Actual visitation, interviewing the Board, Senior management and (scientific) staff. First evaluation of the interviews. Venue Ctgb offices, Ede, The Netherlands
5. 27 June: Mixed face-to-face/video meeting. Discussing findings from a series of dossiers, sorting staff data. Venue: Orange House Partnership office in Brussels, Belgium and home offices in Finland, Italy and the UK
6. 26-27 July; additional individual interviews with 3 staff members; construction of the report, drafting assignment and strict deadlines. Venue: Ctgb offices, Ede, The Netherlands
7. 26 September: Official presentation of the final IVC 2018 Report to the Board, senior Management and all staff. Venue: Ctgb offices, Ede, The Netherlands.

In addition to the face-to-face meetings, the IVC members communicated regularly via video calls and numerous e-mails.

Access to information: Documents

As elaborated in the Action Plan, the IVC was given access to a massive amount of information, mostly as documents but also as minutes of meetings, summaries of discussions internal notes and staff information. The vast majority of these documents are considered as strictly confidential. As elaborated in the Action Plan, the IVC requested information on a large number of issues (see Annexes 5 and 11). After the rather laborious experience with document access by IVC in 2013, the Board and the IVC 2018 agreed that all members of the IVC should have full access to Ctgb's electronic Document Management System (DMS). At its 3rd meeting on 24 April the IVC membership all signed a confidentiality statement not to disclose any document or other written reports without specific approval of the Ctgb management. The access and use procedures of the DMS appeared rather complex and needed, apart from substantial training, also IT support for the installation of tools dealing with various firewall obstacles. Members of the IVC 2018 experienced considerable problems with IT and access to DMS but the technical and scientific Ctgb staff have been very helpful in guiding the IVC members through the labyrinth of the document system.

As expected, a substantial number of significant documents (largely internal notes, minutes and discussion summaries) appeared to be available only in the Dutch language. With only one member speaking and understanding Dutch, dealing with this issue posed challenges.

Access to information: interviews with staff and Board members

On 28 February 2018, at its second formal meeting the IVC met with a number of members of the Board of the Ctgb and senior management at the Ctgb offices. The main purpose of the meeting was for the IVC members to get acquainted with the members of the Board and to review and endorse the Action Plan. A Powerpoint presentation was given by the management and is attached as Annex 6. The Board and the IVC also agreed on the dates of the actual visitation (23-24 May). Furthermore, two additional dates were confirmed i.e. the end of August as the deadline for submission of a draft final report (electronic version) which may be a concise version of the final comprehensive report with annexes. On 26 September the final report will be presented to the Board, senior management, and hopefully all Ctgb staff.

On 23 and 24 May, the members of the IVC 2018 interviewed 7 Board members and the Executive Board Secretary/Director on the role of the Board. The main items for discussion included: transparency and the relationship between risk assessment and risk management. The IVC based their interviews on available CVs, DoIs and minutes of Board meetings. The IVC had prepared a series of 12 questions and sub-questions which were not shared with any of the Board members prior to the interviews. During the same days, the IVC also selected and interviewed approximately 20 staff members, largely from the 4 Scientific Assessment and Advice Teams, the Legal Advice Team, and the Board Advice and Project Planning Team. Staff members were selected based on their function (e.g. Team Leaders) and their expertise and experience as shown in CVs. A set of 22 questions were prepared to facilitate the interviews and, again, the selected staff members were not informed on any of the questions. In order to prevent any possible bias all interviews were done by 2 or 3 IVC members and organized in such a way that any combination of interviewers was unique.

On 29 June the IVC sent 9 additional questions to the Ctgb management asking for further clarification by named staff members on specific issues and allowing a response in writing or as an interview at the next IVC meeting on 27 July. On 25 July, responses were received for 7 out of the 9 questions. The responses for the 2 remaining questions were addressed at the IVC meeting of 27 July.

Access to information: Follow-up on recommendations made in 2013

The report of the first International Visitation Committee included among other aspects a series of 29 recommendations for improvements, see the report of the first visitation (IVC Report of the international visitation of the Ctgb, July 2013). On 18 January 2018 the Ctgb provided the members of the second International Visitation Committee with clarifications why certain recommendations were not or only partly considered for implementation. It appeared that during the last 5 years 17 recommendations were accepted and implemented, 1 recommendation was accepted but has not yet been implemented, 4 were partly accepted and 7 were not accepted.

Annex 7 comprises a table listing the respective recommendations that were not accepted or only partly accepted by the Ctgb, followed for each recommendation by the response of the Ctgb (largely quoted literally). The subsequent comments of IVC 2018 addressing the respective Ctgb responses were made prior to its visitation. The numbering follows that of the 2013 report. The 17 recommendations that were accepted and subsequently implemented are not included in the table. The table content was very useful for the preparation of the second visitation and during the actual visitation. As a first observation the members of the 2013 IVC as well as the new members of IVC 2018 were very pleased to learn that out of the 29 recommendations only 7 were not considered for implementation. From the responses provided by the Ctgb it seems that from the 7 recommendations not accepted at least 3 were interlinked by openness and transparency issues.

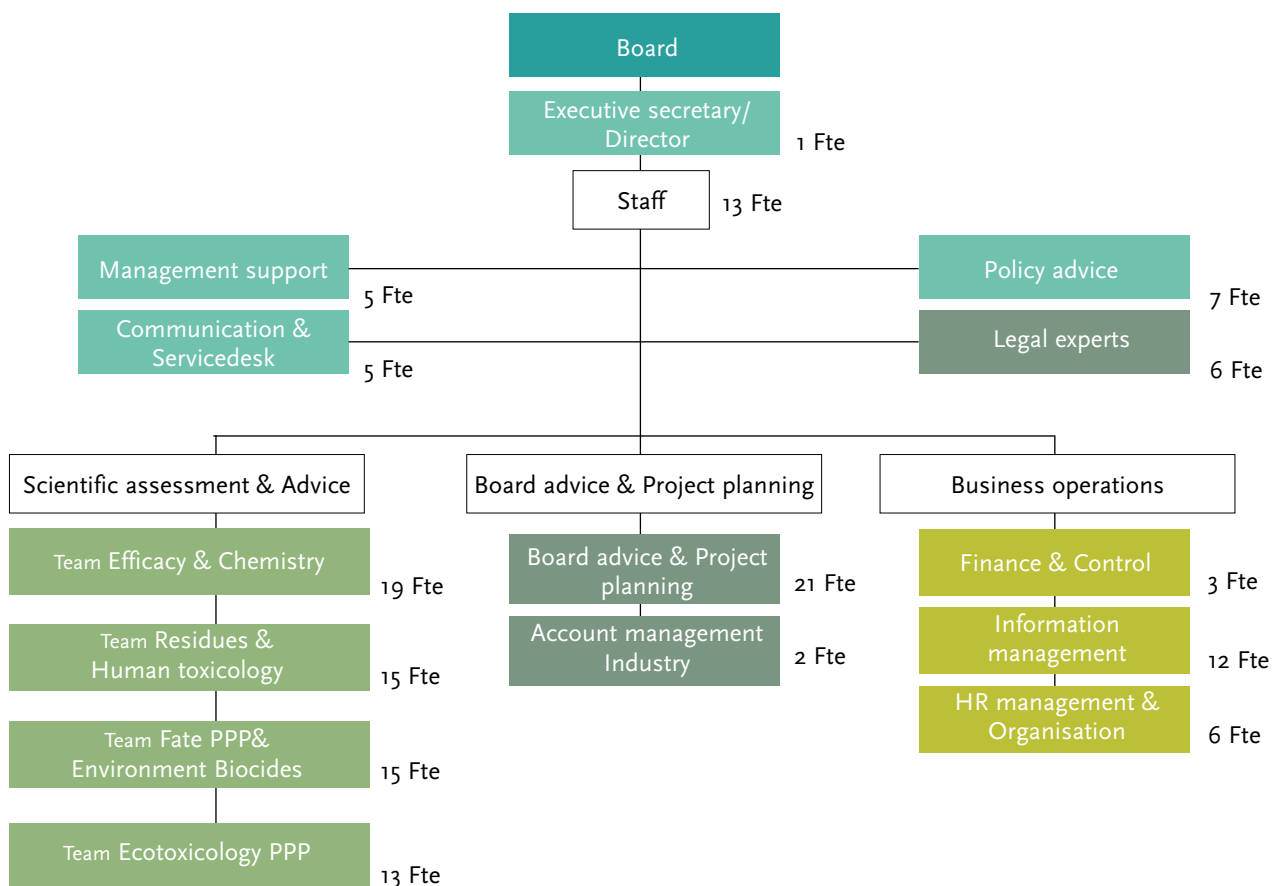
Observations and Findings

Ctgb structure and management

On 1 July 2018 the overall total staff capacity was about 143 Fte which is a considerable increase compared to 2013 (May) when the total was 117 Fte. Approximately 50% of the total workforce is assigned to making scientific assessments of the risks of exposure of plant protection and biocide products to professional users, bystanders and the environment. These experts develop Draft Assessment Reports (DAR) and Competent Authority Reports (CAR) assessing the risks of active ingredients in plant protection products and biocides. The other 50 % of the workforce

assists the scientific staff by providing legal advice where needed, manages a balanced workload for all and facilitates training of new scientific staff. The senior management also support and assist the Board in its Decision-making process. The Board consists of 5 members, including the Chairperson, and 4 substitute members. The Board is supported by the Ctgb Director, who is also the Board's Executive Secretary. The organization structure below provides more details.

Figure 1: Team structure of Ctgb



Human resources and staff policy

Staff information

The structure of the Ctgb has been modified since 2013 to adapt the organisation to be able to manage the increased number of submissions for authorisation of biocidal products and plant protection products. Moreover, at EU level the workload of the scientific staff has also increased with growing scientific activities related to the risk assessment reports for active ingredients in plant protection products (DARs) and biocidal active substances. (CARs). The IVC considered the professional experience and knowledge of the people involved in these activities as important factors in its assessment of the quality and reliability of the organization's scientific output. For this reason, the IVC requested the Curricula Vitae (CVs) of all staff involved, directly or indirectly, in the scientific evaluation process.

The information was collected through a template designed by Ctgb, which includes the basic data requested, such as:

- The current competences in a specific area of work for Plant Protection Products or Biocides.
- The level of education, post graduate studies in toxicology or environmental sciences.
- Number of years of relevant professional experience.
- The record of positions held in Ctgb or in other organizations or companies prior to their appointment to Ctgb.
- Information regarding participation in relevant courses, symposia, congresses, working groups.
- List of relevant publications.

This CV format (see Annex 8) was shared with all employees directly or indirectly involved in the scientific activities with the request to return the completed CVs to human resources within a certain period (14days). It should be mentioned that the responses were very diverse ranging from blank forms to forms partly filled in and a minority of adequately completed forms. The IVC found, during the staff interviews done in May, that some of the staff interviewed had considerably more experience or had participated in numerous scientific activities or conferences that had not been mentioned in their CV form.

In addition to the data collected in the CV template, the IVC requested information regarding:

- Participation in the work of European or International scientific/ regulatory Organizations competent for pesticides/chemicals safety evaluation (for example OECD Working Group on Pesticides, JMPR)
- Participation in the work for EFSA, ECHA, European and international organisations contributing to procedural or technical harmonization. Involvement in the development of particular EU PPP, Biocides Guidance Documents.

The IVC team had access to the Curricula Vitae of 122 staff members, including resumes for 8 Board members. The information has been collected from the CV forms compiled for the IVC, and from the Ctgb web site for that of the Board members. The additional requested information was delivered in several spreadsheets prepared by Ctgb, which were extremely helpful to complete the data gaps from the CV forms.

The following series of figures provides in a nutshell essential information largely about the staff members involved in scientific activities, including members of the Board, the Board advice and project planning team, the Management team, and, as appropriate, the policy advice and Legal support teams.

It should be noted that for the CV information for 16 staff members could not be displayed; there was an identified reason why 11 were missing, but for 4 staff members there was no information about when they were recruited to Ctgb.

Figure 3 shows the number of new staff recruited since 2013. The Figure also shows that the distribution of these 75 staff was not proportional. Although a comparison of these numbers with the those in 2013 is difficult to make for reasons that work assignments to the respective teams of the 'scientific assessment and advice' department have been reorganized and some of the new staff may have resigned, it seems clear that the 'efficacy and chemistry' team has grown substantially.

The highest level of education is one of the criteria considered relevant for the assessment of the quality of scientific output of the Ctgb. Figure number 4 shows the various levels of education, grouped by team. The graph confirms the relatively high level of education with a master's degree as the lowest education level in 6 out of the 9 teams.

Figure 2. Number of Ctgb staff members by team

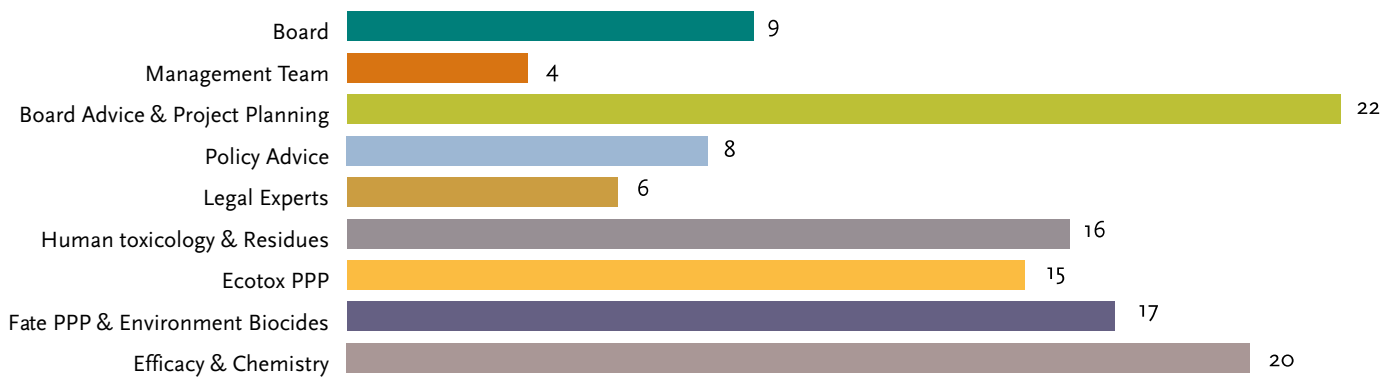


Figure 3. Number of new staff members since 2013

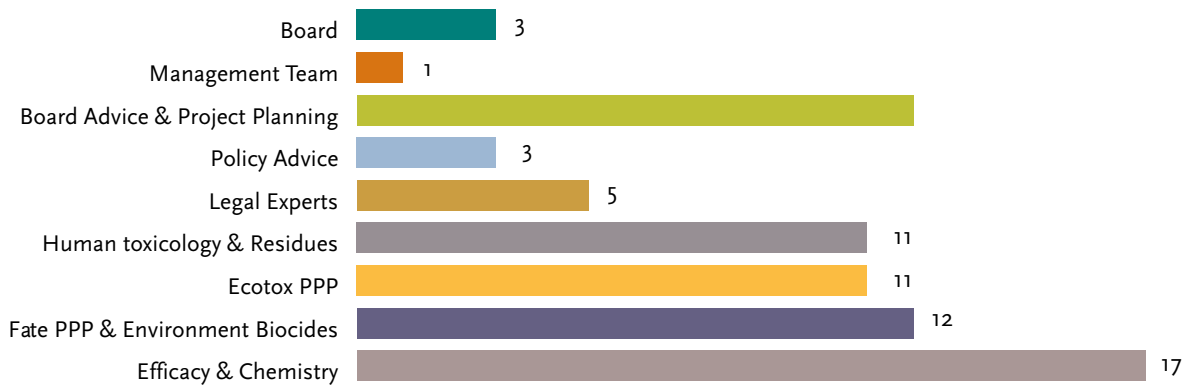
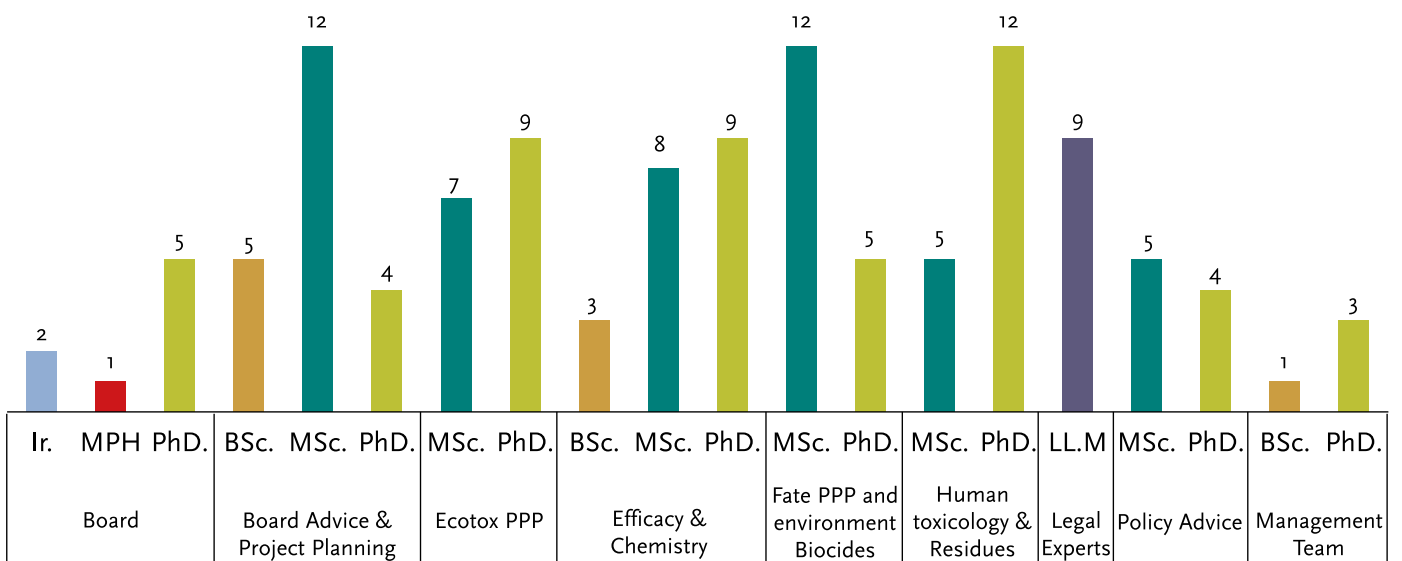


Figure 4. Highest level of education of staff presented for each team



'MHP' stands for 'Master of public health', LL.M stands for 'Master of Laws' and Ir. stands for an academic engineering degree.

Surprisingly, the IVC noticed that not all eligible staff members are formally recognized as European Registered Toxicologist (ERT), for instance, none in the area of environmental toxicology. Most likely the criteria for the application would be met by several additional staff members, in particular, in environmental toxicology. The IVC highly recommends for HR to stimulate scientific staff to apply for the ERT recognition. Information can be found at: <http://www.eurotox.com/ert/how-to-become-an-ert/> One staff member of the 'Board advice and project planning' team did not provide information about education but provided sufficient information to conclude that the person has solid experience in the relevant area. This person is not considered in this graph.

Next to the education level, professional experience is considered an important indicator of the science output. Figure 5 shows for each team the average number of years of relevant experience before and after joining Ctgb. The source of this information is the available CVs. It should be noted that there was no information on experience before joining the Ctgb for 6 legal experts, 5 staff members of the Fate PPP & Environment Biocides team, 2 members of the Ecotoxicology team, 1 member of the Human toxicology and residues team, and 14 members of the team Efficacy and Chemistry.

Although deepening scientific knowledge is not considered to be a priority in Ctgb staff policy, the IVC did consider the number of scientific publications as part of the evaluation of the staff's scientific background and knowledge level. The information in Figure 6 is focused exclusively on the Scientific assessment teams and shows the number of relevant publications per team and the number of publications for which a member of the teams is 1st author. All risk assessment teams have produced an important number of relevant publications, and a significant figure as first author. The numbers of publications per team reflect well the highest education level of each team. It should be noted, though, that the majority of the publications were developed during the PhD programs previous to their recruitment by Ctgb.

In order to assess how the Ctgb keeps up-to-date with scientific developments in human and environmental risk assessments, the CV format also asked for information about participation in relevant training courses, symposia,

congresses, etc. The IVC specifically asked for information about participation in conferences as a speaker in the Netherlands and abroad on scientific issues concerning the risk assessment of plant protection products or biocides. Participation in training courses concerning safety assessment of PPPs or biocides and in the work of European or International scientific or regulatory organizations competent for pesticides or chemicals safety evaluation was also considered to be relevant.

The numbers for each team shown in Figure 7 are the averages of the total number of attendances per individual staff member. Hence these numbers are not the total number of conferences, or participation in trainings, or working groups.

As the information provided by the CV's available was often sparse, the IVC was not able to draw firm conclusions. However, some observations of interest include:

- The majority of scientific assessors participate regularly in training courses relevant to their area of work
- Some of them are invited to present lectures in specialized workshops.
- Risk assessors participate in various European regulatory or scientific working groups mainly in EFSA and ECHA as well as their participation in the development of guidance documents applicable to the risk assessment of plant protection products or biocides.

Furthermore, while producing less publications, the Ecotox PPP team appears to be very active in conference participations, working groups and training courses. Ecotoxicology certainly is an area of continuous international development.

Staff Policy

Work climate

When in February 2018 the IVC members entered the offices of the Ctgb for the first time, all members and particularly the three members who had also been members of the IVC in 2013 were pleasantly surprised by the warm welcome. The contrast with the cool reception 5 years ago could not have been more striking. Throughout the actual visitation on 23 and 24 May and again on 27 June, the contact with all

Figure 5. Average years of experience in Ctgb and before Ctgb by team

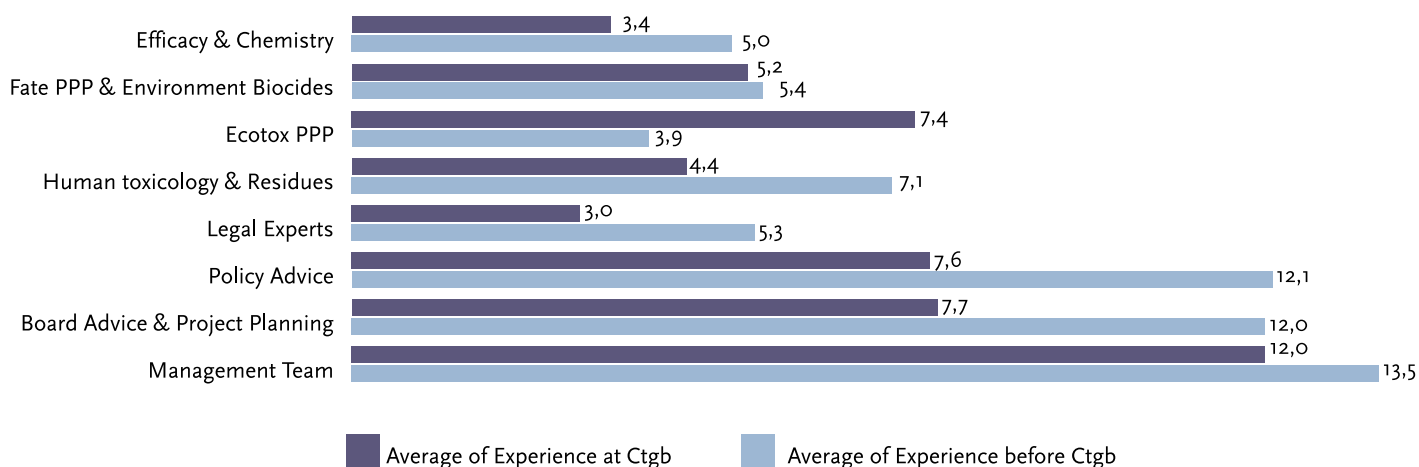


Figure 6. Scientific Publication per team and first author publications

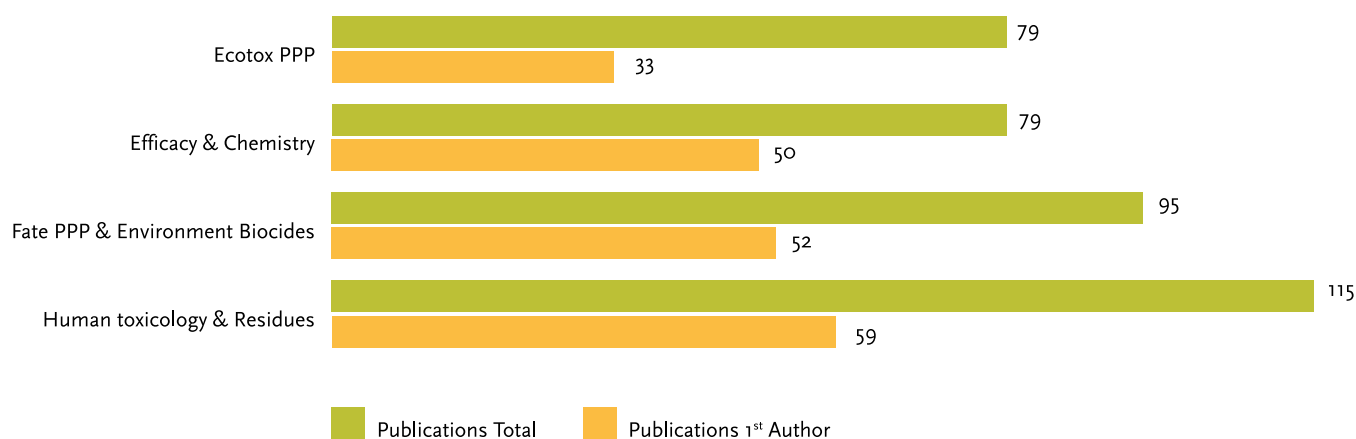
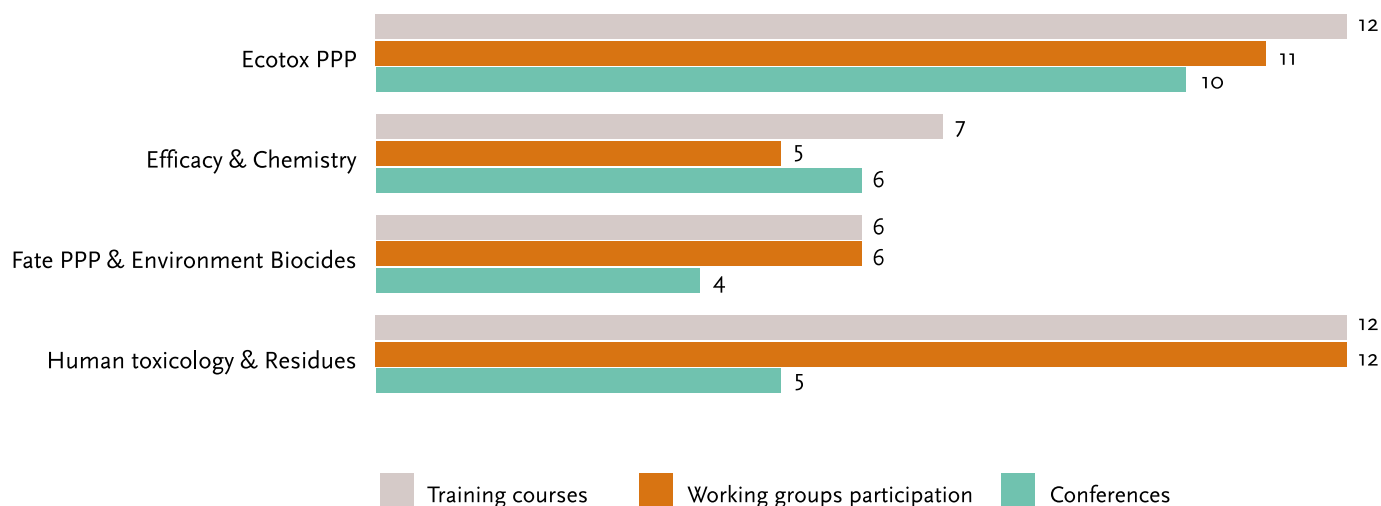


Figure 7. Conference participation, working groups and training courses per team



staff at all levels has been helpful, pleasant and forthcoming. Moreover, the IVC noticed that this culture of collegiality was also present amongst the staff. The overall atmosphere was one of confidence.

While, contrary to 2013, access to documents, reports, notes, etc. was unlimited, it appeared that the staff in general were not eager to provide personal information to the IVC. The CV form developed by the Ctgb (see Annex 8) and agreed by the IVC as the minimum level of information, was supposed to have been fully completed by all the 122 staff members directly or indirectly involved in science activities. However, as explained in the previous section, the return was rather poor.

A major management decision has been to stick to one general job description for scientific risk assessors without promotion grades implying that all scientific risk assessment staff are in the same salary scale and their remuneration differs only based on the number of years at Ctgb. Once the top of the scale is reached, their salary is fixed. From HR management, the IVC learned that an employee satisfaction survey revealed that Ctgb employees (eg scientific assessors) value responsibility, challenging tasks and diversity in their function more than the financial compensation as such. This equality of remuneration has resulted in a level working environment where the workload is as much as possible evenly spread among the experts. Each team has its own “bucket list” in which it finds the work assignments for the coming 2 weeks. Team leaders are free to divide tasks among team experts. From staff interviews the IVC learned that indeed the majority of randomly selected staff members are content with this approach. Although a minority appeared to be less happy with the system, in particular because an annual non-transparent bonus system, introduced a few years ago, creates some unrest even though the size of the bonuses are relatively small. The members of the IVC suggest that there may be a link between the flat remuneration level and the apparent disinterest in providing properly detailed CVs and DoIs. The lack of incentives other than a bonus system without selection criteria and transparency, in time may become a cradle for lethargy and indifference among sensitive staff. On the other hand, the earlier mentioned atmosphere of congeniality amongst staff would suggest the contrary.

The IVC is of the opinion that the bonus system could be reconsidered by making the selection procedure transparent

and based on defined selection criteria. A simple blind voting system with one trusted independent outsider might be sufficient to improve the system.

IVC members recognize that staff expertise and experience are values to be proud of. A greater effort could be made by the management to raise awareness amongst the staff of the importance and relevance of their tasks and responsibilities for the health and safety of society and the environment. A healthy organization needs dedication but also ambition and competition.

Education and training

Deepening an individual's scientific knowledge is not considered to be a priority in Ctgb's staff policy. As a consequence, drafting scientific publications is not stimulated and no capacity is allocated to such activity. As explained in the text clarifying figure 6 above, the majority of staff publications were written during previous positions elsewhere or written as PhD students prior to their appointment by the Ctgb. Nonetheless, a significant number of publications by Ctgb scientists (rather close to 100) have been published since 2013.

The IVC was pleasantly surprised to learn from the HR management that as part of the revision of the staff policy for all staff:

- There is personal yearly activity plan including the need for or wish to follow a course, to attend a conference, to undertake specific training, etc.
- All scientific staff are given 100 workhours each year to be used for their further personal development without accountability conditions.

Outsourcing

The IVC is aware that with constraints related to legal deadlines and temporarily limited capacity outsourcing of parts of a dossier may be necessary on occasion. The IVC noticed that for certain PPP assessments the equivalency assessment was outsourced because of “lack of manpower”. The IVC is concerned about outsourcing and addressed this in its 2013 report specifying that outsourcing should be restricted to highly specialized areas of expertise not available at the Ctgb. In this particular case outsourcing concerned the equivalency assessment of a number of active substances in their products which is a basic and first-step assessment and normally does not require a very specific expertise. Furthermore, this assignment was trusted to a

commercial contract laboratory with close contact with Ctgb Hence, a potential conflict of interest apparently not registered.

Declaration of Interest

As addressed elsewhere in this report, openness and transparency are the pillars of trust and mutual understanding. Annual declarations of interest to DoI are a tool providing such insight, in order to share with peers and to openly consider when a particular interest may become a conflict. Such a conflict is usually described as an undue influence on the person's objectivity with respect to his/her task and responsibility.

Ctgb's current policy about potential conflicts of interest includes that:

- Each staff member is required to declare his or her interests yearly to the management. It is the responsibility of the Director and the Board to scrutinize the DoIs
- If a staff member has worked on PPPs or biocides in the private sector prior to joining the Ctgb, he/she is not allowed to work on dossiers of that company for 2 years.
- Collegiate peer review of documents is considered a pragmatic way to check or minimize any undue influence by an individual staff member.
- Only interests that could possibly be (or perceived to be) in conflict are listed in the DoI.
- The staff code of conduct does not allow the acceptance of any gift.
- The DoI includes only personal interests and not those of spouses or family members.

On request the IVC received a series of completed DoIs of staff for the last three years and randomly selected a sample to examine (see Annex 9). On the basis of information obtained, the IVC is of the opinion that the current policy clearly falls short and is not in harmony with international standards. In addition, the level of compliance is very low. Only about 50% were signed in 2015; the rest in 2016 or 2017. The IVC 2018 appreciates the comprehensive and informative guidance for the completion of the Declaration of Interest forms (DoI) (at the Ctgb intranet: Toelichting bij formulier 'nevenwerkzaamheden') but is of the opinion that without addressing direct and indirect material or immaterial interests, collecting information only about side jobs is a futile endeavor.

The IVC is of the opinion that yearly reporting of all relevant interests by every staff member may be satisfactory only in cases where there are no significant changes in position and/or in links with the outside world. Furthermore, the IVC supports the international position that staff members who have worked for industry before joining the Ctgb, should not work with dossiers of that particular company for at least three years. Considering the often very long timeframes of risk assessment work, the term of three years is rather short.

Openness and transparency

From time to time the Ctgb comes under fire from the media, the professional users, and/or non-governmental organisations challenging a decision of the Board or the scientific assessment report. Being aware of these public challenges, the IVC 2018 strongly believes that showing openness and transparency to demonstrate the Ctgb's independence at all phases of the risk assessment and subsequent risk management, are the only instruments needed to avoid being driven into a corner from where defense is the only option. Moreover, a defensive stand has been proven many times in various situations to be very poor and not credible.

Openness and transparency

(see Annex 10 for Powerpoint slide)

Openness and transparency are globally considered as the two pillars on which 'trust' is built. Although the words partially overlap, they have slightly different meanings: 'Openness' stands for honesty and reliability while 'transparency' means showing all information on the relevant issue. As an example : when an annual report about coal mining in the USA shows in a graph that the number of accidental deaths per million tons of coal mined has gone down over the years, these figures are definitely transparent. But when the number of accidental deaths per 1000 coal mine workers is shown during the same period, that graph shows a significant increase in the number of casualties. Both graphs are correct and transparent, but only if presented side by side is there also openness. The second graph was not included in the annual report.

Distinguishing risk assessment from risk management

For reasons of openness, transparency and public trust, it is important that the rigour and robustness of the risk assessments are visibly separated from the complex risk management discussion and decision process that may or may not result in authorisation. After lengthy discussions with the Board and the Ctgb Management, the IVC 2018 is of the opinion that the strongest reason for separating risk assessment from risk management is that the latter considers in its decision-making additional and equally valid elements such as economic, agricultural, religious/ethical and political consequences. Distinguishing and separating these equally relevant risk management components and decisions from the science-based risk assessment makes the whole process transparent and strongly contributes to building public trust (see also the chapter on legal support). The Board appears comfortable with its responsibility to take the risk management decisions underpinned by sound technical risk assessments, and claims that since it is composed of experts, that its risk management decisions are also primarily science-based. However, it is not clear how the latest science within the field of risk management is taken into consideration in the individual product decisions, e.g. how in practice preference is given to 'green' or 'low-risk' products in its workflow or how transition to integrated pest management and sustainable farming systems is stimulated by its decisions. Whilst all the documentation recorded in the excellent and comprehensive internal Document Management System of the Ctgb was available and traceable for the IVC, this is not the case for the general public.

Only the assessment report after the Board discussion together with the authorization decision is made publicly available to the external world. All other reports are considered to be drafts, not meant for publication. In specific cases, when the determining factors are considered relevant for the general public, the Board also communicates the rationale of its decisions on product authorization in a press release. In most cases when explanations are required, also included are the decisions on non-authorization, risk mitigation measures, early adoption of developments in the assessment framework, or modifications of proposed decisions. The press releases are in Dutch as the target readers are considered to be pesticide users, Dutch NGO's and the Dutch public. In general, only the Assessment Reports are published in dual language (Dutch and English); most other relevant documents appear to be in Dutch,

including the conclusions of Authorization decisions.

Taking note of the strong preference of the Board to make its decision both on risk/safety assessment and risk management, full transparency of the process seems to be the only solution to enable distinguishing one from the other. This could be achieved by formally assigning a senior responsible representative of the science department (e.g. the Chief Scientific Officer CSO) as a non-voting attendant and advisor to the Board during its decision-making discussions. In addition, minutes of decision making meetings should provide sufficient details of discussions to permit distinctiveness in recognizing management from scientific arguments.

In order for non-Dutch-language-understanding professional experts to follow and understand such discussions in written records, the need for translation into English seems inevitable. The IVC recognizes the primary need to communicate with Dutch stakeholders as well as the general policy of the Netherlands to protect the national language. However, the translation into English of publicly available documents will increase the transparency to the external world, primarily the other Competent Authorities of EU Member States.

Openness and transparency in communication

As a national, unified, regulatory authority engaged internationally with other similar regulators, the Ctgb undertakes both the scientific risk assessment of PPPs and biocides and their products, including assessing the likely impact of mitigation measures, and also takes risk management authorisation decisions based on the assessment reports and consideration of broader context and wider issues (e.g. agricultural, economic, environmental, societal). Openness, transparency and the development of public trust require clear, effective and open communication with the outside world, which includes both Dutch stakeholders and the wider international regulatory community.

Openness and transparency in tracing the full assessment and evaluation activities trail

The IVC 2018 is pleased to note the recent effort of the Ctgb in developing its internal Document Management System (DMS). When used properly and all documents have been recorded in the system in a timely fashion, the DMS greatly increases the availability of the documents

and thus the efficiency of the scientific process within the Ctgb. The observation of the IVC 2018, based on its own user experience during the evaluation and visitation, however, is that tracing the full assessment and evaluation activities of individual products may be challenging. While being an ambitious system, the complexity of the DMS may result in differences between individual project leaders and other staff members in using it, as appeared in their actual practices of timely recording documents into the DMS. Therefore, continuous internal training for and streamlining of working practices by individual staff members might be useful to get the best out of the system thus ensuring transparency between individual applications and the equal treatment of different customers and other interested parties.

Openness and transparency in human resource management

The IVC 2013 suggested and recommended that, for transparency reasons, the Curricula Vitae (CVs) of all scientific staff, senior management and the Board, as well as those contracted to undertake evaluative work on behalf of the Ctgb, be made publicly available on the Ctgb website, preferably in the harmonised EU format. The IVC 2018 is disappointed with the decision of the Ctgb not to adopt this recommendation. The IVC 2018 is astonished that such an enormous pool of excellent knowledge and skills to be proud of is unnecessarily hidden because the CVs of the scientific staff are still not made publicly available. The Board clarified its decision by explaining that only staff with recognized responsibility are considered, and that this is supported by the new Dutch privacy law.

While respecting the Dutch privacy legislation, the IVC 2018 considers the decision to publish only the resumes of CVs of individuals with a formal mandate in assessment and decision making as inadequate and lacking openness. This is in contrast to both EFSA and ECHA where full CVs and Declarations of Interest (DoIs) are published for Board members. The IVC 2018 strongly recommends that the Ctgb Management reconsiders its reticence about openness and transparency, in particular with respect to the level of detail and accessibility of CVs and DoIs of scientific risk assessors. In this context 'accessibility' may already meet transparency by providing access to CVs and DoIs of all scientific risk assessors only upon written request. Full openness could be reached by demonstrating the excellent level of expertise of the Ctgb and making the CVs and DoIs

of all scientific staff accessible. As a minimum the level of education, area of expertise, and years of experience (both before and at Ctgb) of the scientific risk assessment staff should not be considered as confidential information but be made accessible. This recommendation should not be seen as an offence against personal privacy but rather as a means for proudly highlighting the excellent expertise and high scientific level of the staff as a whole.

The IVC welcomes the currently used CV format for all staff involved in Ctgb's scientific activities. However, the IVC strongly advises that all CV's are properly completed and updated, as appropriate, at least once a year.

Evaluation of scientific process and scientific output

The tasks assigned to the IVC 2018 in the ToR, and agreed upon in the Final Plan of Action (see Annexes 1 and 5), included the assessment of the scientific quality of the evaluations conducted by and the authorisation Decisions made by the Ctgb of plant protection products and biocides; the level of legal compliance with EU and national regulations of the formal risk assessment and decision-making processes and related outputs of the Ctgb; and the effectiveness of Ctgb arrangements to foster the authorisation of 'green' or 'low-risk' products and to stimulate transition to integrated pest management and sustainable farming systems (see Annex 12).

The Ctgb participates in the EU process for approval of active substances. This activity includes drafting assessment reports as rapporteur member state (RMS), for active ingredients in biocides (CARs) as well as plant protection products (DARs and dRARs). Furthermore, the Ctgb also reviews extensively assessment reports produced by other member states. The IVC has easily retrieved lists of DARs and dRARs and CARs that NL was responsible for since 2014.

In the action plan, the IVC requested amongst other information a list of DAR's and product authorizations granted since January 2014 (see Action Plan in Annex 4, section 10: k). It was the intention of the IVC to select some DAR's and evaluate the risk assessments of these new active substances and the product authorizations and mutual recognitions that build on these DAR's. However, yet no products are authorized based on the DAR's mentioned in the list delivered by the Ctgb.

The reason for this is the lengthy process of active substance approval following the moment that Ctgb finalizes the DAR, and which includes EFSA that issues its conclusions, and approval or non-approval by the Standing Committee for Food Chain and Animal Health. Theoretically, it takes 1.5 years from finalization of the DAR to substance approval, but in general this is 2.5 years. Thereafter, it takes 1 year for product authorization. For active substance renewals, applicants have the opportunity to perform studies (Category 4 studies) in case of data gaps, which may take another 2 years.

Therefore there are not yet product authorizations derived from the active substances in the list of DAR's where the Netherlands is the RMS finalized after 1 January 2014. The same applies, more or less, for biocide active substance approval and biocidal products. Therefore the IVC was only able to scrutinize the draft Renewal Assessment Reports (dRARs) of existing active substances prepared by the Ctgb. In order to fulfill these tasks the IVC members conducted an in-depth evaluation of the scientific process and scientific output by scrutinizing a number of selected dossiers prepared by Ctgb:

- Draft Renewal Assessment Reports for 3 plant protection active substances. One of them still not concluded.
- Draft Renewal Assessment Report for 1 plant protection low risk microbiological active substance, still ongoing.
- Competent Authority Report for 1 biocidal active substance.
- Decisions on authorization of 7 biocidal products.
- Decisions on authorization on 5 low risk biological plant protection products.

The evaluations of the selected dossiers and Board Decisions were done by individual members of the IVC and reviewed by all other members. A common grading system was applied based on criteria developed prior to the respective reviews.

The findings and observations of the IVC were compiled in relation to the criteria originally developed for the 2013 visitation and amended for the 2018 visitation. The criteria included:

- Confirmation of compliance with adopted guidance and legislation,
- Clarity and comprehensibility in terms of data available and data utilised,
- Weight of evidence considerations, variability and

uncertainties and assumptions, conclusions and recommendations,

- Evidence of collegiate feedback and/or peer reviews
- Level of consistency and coherence with other dRARs / CARs
- Evidence of international recognition and acceptance
- Level of adequateness of response to comments, questions and suggestions.

For the accomplishment of this task the members of the IVC were given access to the heavily protected Ctgb Documentation Management System (DMS) and all documented information of the selected dossiers. For nonregular users of the DMS access to and use of the system was like being in a labyrinth, the more so when it appeared that for several dossiers the filing of specific documents was rather complex. Therefore, the assistance and guidance provided on this issue by the Ctgb staff was greatly appreciated.

The common opinion on all findings and observations agreed by the IVC members are summarized below grouped by active substances and products.

Dossier evaluation and risk assessment active substances

Criterion 1: Compliance with legislation and relevant guidance documents.

- The IVC members verified the compliance with current legislation and specific guidance documents applicable throughout all the work flow of the dossiers for which NL was the RMS, from the pre-submission meetings to the peer-review and final dRAR or CAR, evaluating the compliance with legislative requirements, application of EU guidance and compliance with deadlines. The CAR and dRARs investigated were renewals of active substances.
- With respect to the evaluation of the selected plant protection products (PPP) and biocide products (BP) the work of the scientific staff appeared high-rank and in line with the up-to-date EU guidances and legislation on pesticides and biocides.
- In one of the DARs there was an externalization for the assessment of equivalency of the active substance in their products to a contract laboratory, due to temporary lack of manpower. In the correspondence with the Applicant it is highlighted that outsourcing caused some delay, albeit without serious consequences. The Ctgb has further clarified that all

assessments produced through outsourcing are peer-reviewed by the Ctgb staff.

Criterion 2: Clarity and comprehensibility of the Scientific opinion specially in terms of data available and data utilised.

- There were significant data gaps in some of the dRARs investigated, some of them required expert consultation and stopping of the clock of the deadlines. In these cases, the Ctgb properly addressed them using clear, strong science-based arguments, and maintained a fluent communication with Co-RMS, EFSA, other MS and applicants.
- The information prepared by Ctgb in the dRARs and CARs reviewed has a high level of clarity and comprehensibility.
- The presentation of data available and their use was clear, complete and understandable.
- In those assessment reports where critical areas of concern were identified they were clearly marked and included conclusions reached during peer review.

Criterion 3: Weight of evidence considerations, variability and uncertainties and assumptions, conclusions and recommendations.

- In the dRARs and CAR reviewed, the evidence appeared to be accurately considered and weighed, when there were areas of concern identified.
- Two critical areas of concern were identified in the dRARs scrutinized, where the opinion of the Ctgb disagreed with EFSA and other MS. These concerns can be pivotal for the permanence of the substance in question in the EU market. In both cases, the Ctgb held its positions with scientific arguments. The IVC notes that such disagreements are almost customary in the peer-reviewing process, and the points for disagreement were relevant to the interpretation of EU guidance. Apparently, there is no specific and consistency policy for a feed-back discussion of the outcomes, also the Board does not appear to be involved. At least in one of the cases there was no recording of the internal discussion at the DMS and the weight of evidence that support it.
- In the CAR reviewed the conclusion was that the earlier risk evaluation is still applicable for the renewal though it was not possible from the documents to identify whether this evaluation was made by the applicants or by the evaluator.

Assumptions and uncertainties were identified but are assumed that they would be effectively reduced by the imposition of restrictive and extensive Risk Mitigation Measures, which are agreed at the EU level as necessary conditions for approval of this active substance.

Criterion 4: Evidence of collegiate feedback and/or peer reviews of drafts.

- All the comments and correspondence with Co-RMS, EFSA, ECHA, MS and applicants were properly recorded in the DMS system and clearly documented and classified. Although there were some empty folders and some of them were in Dutch it was possible to trace back most of the information.
- The reflections of the Ctgb on the comments of Co-RMS, MS, ECHA and EFSA appeared to be well-founded, scientifically sound and clear.
- There is evidence of internal peer review at the Ctgb in the form of e-mail discussions as well as in the Board documentation, which are recorded in the DMS of the Ctgb.
- Considering the remarks/disagreements with EFSA and other MS, apparently not all correspondence was always clearly documented in the DMS. The disagreements are highlighted in the dRARs, which address the critical areas of concern. In two cases examined the disagreements in the assessment concerned different interpretation of EFSA guidance and criteria between the rapporteur MS (Ctgb) and the peer-review. This interpretation led to a feed-back discussion within the relevant Ctgb team (ecotoxicology), but apparently the Board was not involved.

Criterion 5: Level of consistency and coherence of the dRAR and CAR with other dRARs and CARs.

- In general, the level of consistency and coherence of the reviewed dossiers was in line with other CARs and dRARs prepared by other Member States.
- From the reviewed dRAR for a microbiological active substance it appeared that the dossier is not finished. However the conclusions drawn so far were in line with other microbiological active substances evaluated by other MS and peer reviewed within the EFSA process.
- In a dRAR of an active substance the assessment process is still ongoing. So far the process is in line

with similar dRAR in other MS. However, in view of the complexity of the dossier and the significant amount of issues found on critical areas, the IVC was unable to make a full evaluation of consistency and coherence given the timeframe of the visitation.

Criterion 6: Evidence of recognition and acceptance of the dRAR or CAR by EFSA, ECHA, EU member States.

- The dossiers reviewed by IVC members have a high scientific quality and were well accepted by EFSA, ECHA, Co-RMS and other Member States.
- When there were minor comments made by EFSA, these were amended by Ctgb.
- The reflections of the Ctgb on the comments of Co-RMS, other MS and EFSA appear well founded, scientifically sound and clear, even when not accepted they were sound and helped the elaboration of the assessment.

Criterion 7: Level of adequateness of the response to comments, questions and suggestions from Member States' experts.

- There was sufficient evidence that the comments received by Applicants, EFSA, ECHA, and MS were responded to adequately, and the answers given were clearly formulated, and properly registered.
- In general, the processes appeared to be transparent and clear.

Dossier evaluation, risk assessment and authorisation decisions of plant protection products and biocidal products

The IVC reviewed the dossiers and authorisation decisions of 5 microbiological plant protection products, 4 of them were renewal of interzonal core evaluations prepared by other MS and one for mutual recognition. In all of them the documentation was easily available in the DMS system. Additionally, seven representative formulation dossiers and decisions were reviewed in connection with one biocidal active substance risk assessment prepared by the Ctgb.

Criterion 1: Confirmation of compliance of the Decision with adopted guidance and/or legislation.

- The assessment documents on biocidal products and plant protection products produced by or contributed to by the Netherlands were found to be in compliance

with the relevant and the current EU guidances and the biocides legislation.

- The evaluation of the selected low risk plant protection products confirmed that the national Risk Assessment and the Decision appears to follow the EU legislation on mutual recognition and data requirements for microbial pest control agents laid down in the Commission Regulation 284/2013 for plant protection products.

Criterion 2: Clarity and comprehensibility of the Decision especially in terms of data available, data utilized.

- For the selected biocidal products assessed, the clarity and comprehensibility of the Assessment Reports are high. Additional data were evaluated logically and the conclusions reached are clear. Considered views are contributed to the between-MS evaluation of zonal data and documented exchanges.
- In the various dossiers and decisions about Microbiological Pest Control Agent (MPCA) products reviewed, the national assessments made by The Netherlands are largely well prepared.
- There was a clear argumentation for waiving certain data on these low risk active substances.
- When a hearing period before release to the market was launched for products with active substances previously not authorized in the NL, there was no evidence of new specific issues appearing during the hearing.

Criterion 3: Weight of evidence considerations.

- No discrepancies were found in the conclusions which are clearly based on the data and supporting documentation provided.
- The argumentation for waiving certain data for a specific dossier is well justified and discussion between the risk assessor and the applicant is excellently documented.
- Low risk was concluded in all MPCA products selected: in one dossier the national evaluation is not available yet, in another the efficacy testing is the main issue in the Dutch addendum to the zonal risk assessment, in others precautionary statements and adequate mitigation measures were included in the Decision to protect user and non-target organisms.

Criterion 4: Evidence of collegiate feedback and/or peer reviews of draft Decisions.

- The IVC found it difficult to assess since most documents, including the conclusions of the Board's Authorisation Decisions, since they were solely in the Dutch language, except for the Assessment Reports which are in dual language (Dutch and English). When exchanges of comments were in English they all show clear and well-argued reasoning.
- Concerning the MPCA products there was no documented evidence of internal peer review apart from the discussion of the Board. Even when a peer review was most certainly expected because, in one case there was a significant number of new studies to be evaluated first time since the EU evaluation of the active substance, no evidence of peer review could be found.

Criterion 5: Level of adequateness of the response to comments, questions and suggestions of the Board.

- In the Biocidal products dossier the evaluation of comments from other MSs appear to have been considered. Some were accepted, based on clear scientific arguments, while others were not.
- In general, correspondence with the applicant was well documented in the DMS, and the evaluation and decision process were well traceable in the DMS. However, in one of the MPCA products reviewed the continuum of the documentation in the Ctgb DMS was not very easy to follow as documents concerning some other products and active substances were filed in this folder, obviously for the purpose of comparison, but that was not explained.

Overall statement on the scientific process and output

For nonregular users of the DMS access to and use of the system was not easy, the more so when it appeared that for several dossiers the filing of specific documents was rather complex. The assistance and guidance provided on this issue by the Ctgb staff was appreciated. Once familiar with the system, the documentation in general is easily traceable due to well-organised files, but in some cases was difficult to fully track which Board meeting discussed the risk assessment.

The overall impression of IVC members was that the different roles of Ctgb as (rapporteur) RMS, (commenting) CMS and mutual recognition MRS were conducted effectively, clearly and, as far as could be retrieved and understood (from a language point of view), with scientific knowledge, a sound use of up-to-date guidances, and appropriate documentation.

The dRARs and CAR reviewed were well prepared, transparent and the areas of concern are clearly indicated and are accurately considered and weighed, in compliance with up-to-date guidances.

Generally, the comments of the Co RMS, MS and EFSA or ECHA were properly addressed and all conclusions of peer review were properly recorded.

There is evidence of internal peer review of the Dossiers within the Ctgb and the Board. The IVC appreciated that since 2013, the Board of the Ctgb continues to undertake a systematic review of DARs, dRARs and CARs prepared by the staff prior to submission to the European Commission, EFSA and ECHA. This approach is endorsed by the IVC as good practice and should be continued.

However, on some relevant issues in the dRARs reviewed, the final conclusions after the peer-reviewing at the European level were not in agreement with the RMS. Although these discrepant interpretations were discussed within the Ctgb risk assessors, it is unclear whether the Board was involved.

The overall process of risk assessment and decision on MPCA products is well traceable and transparent in the DMS. Currently, the decisions of the Board are well justified and supported by data and communicated with the applicant during the application process. However, for some low risk products, no evidence was found of internal peer reviews of the risk assessment of the products recorded in the DMS, before they went to the Board.

The Dutch National Addenda reports that were finished are well prepared, transparent and include precautionary measures to avoid environmental contamination when they are required. The decisions are in line with the EFSA conclusions on low risk MPCA active substances.

Scientific Outreach

The IVC appreciates the policy of the Ctgb to realize a transition from a traditional to a more sustainable agricultural production, specifically by supporting the development of non-chemical and Integrated Pest Management (IPM) practices. The active contribution of the Ctgb to authorizing and releasing biological and low-risk pesticides on the market is highly valuable and as one of the front runners, promotes the conditions of organic farming in Europe. This policy indeed supports the target of the Sustainable Use Directive 2009/128/EC. The IVC warmly encourages the Ctgb to continue on this path.

Also, in international working groups of EFSA and ECHA Ctgb experts are very active in guidance development and refinements. Not surprisingly, it was the Ctgb that took the initiative to create a forum of directors of national competent authorities involved in the authorization of PPPs and/ or biocides in the Central European Zone to work towards mutual understanding and trust. The IVC recognizes and commends this initiative.

Reflection on the recommendations of 2013

As a first observation the members of the IVC 2013 as well as the new members of the IVC 2018 were very pleased to learn that out of the 29 recommendations only 7 were not accepted and implemented (see Annex 7). From the responses provided by the Ctgb it seems that of these 7, at least 3 recommendations were interlinked by openness and transparency issues. Each of these three recommendations pointed to a specific step in the process of making final decisions by the Board. The aim of the IVC in 2013 was (and still is today) to be able to identify and separate which elements of the decision-making process and discussions are based on unbiased scientific risk assessment and which elements are based on risk management considerations. Taking into account the strong position of the Board to decide both on risk/safety assessment and risk management, full openness and transparency of the whole process seems to be the only solution to enable distinguishing one from the other.

Indirectly related to decision-making was the Ctgb's position to limit access to CVs' to members of the Board and the Director/Secretary of the Board. CVs of other staff members involved in risk assessment are not published on Ctgb's website. Reasoning for that decision was that only these individuals have a formal mandate in assessment and decision. The IVC 2018 is of the opinion that in addition to the current level of transparency in the profiles of these individuals, Board decisions will be stronger when the level of scientific education, experience and expertise of those staff members, who provide the basis for each Board decision, are accessible, rather than hidden in the files of Human Resources.

Legal support

Mandate and role of the Ctgb

The Ctgb as a Government agency has mandated national responsibility for both the risk assessment and the risk management authorisation of plant protection products and biocides.

The IVC notes that the "Decree on the Mandate, Authorisation and representation by the Ctgb, 2011", the Decree on the "administrative regulations for the authorization of plant protection products and biocides Ctgb 2007" and the "Regulations for the Working Methods of the Board" required updating following the publication of the Plant Protection Products Regulation 1107/2009 and the Biocidal Product Regulation 5268/2012. The revisions will describe the functions of the Board, its Chairman and the secretary/director with precision, thereby avoiding any uncertainty or ambiguity with regard to their responsibilities and mandates. The IVC fully endorses the considerable efforts of Ctgb to finalise the update of decrees recognising that part of the responsibility of the revision is beyond the Ctgb. The seriously overdue publication of decrees is expected at the end of 2018.

In support of the quality, consistency and management of the technical assessments and recommendations prepared for the Board, the IVC commends the recent introduction of the comprehensive screening and monitoring of the assessment framework cycle, which includes all assessments produced and decisions subsequently taken. There are

two coordinators who organise this contribution to the internal peer review process which provides web-access for applicants and assessors. Currently the peer-review of the overall assessment which ultimately becomes Appendix II of the authorisation, is performed by one Project Leader. This would benefit from the wider involvement of the relevant scientific experts.

Legal aspects

The Ctgb legal team is involved mainly with confidentiality/ data protection issues and related Court decisions, whereas issues related to conflict of interest take up negligible resources. Complaints and appeals as well as well-founded objections are relatively infrequent; an overview of the years 2014-2017 is presented in Tables 1 and 2.

Table 1. Numbers of objections and complaints and their outcome

Year	Objections	Well founded	Complaints
2014 ¹	66	10	2
2015 ²	47	9	2
2016 ³	34	5	1
2017 ⁴	46	12	0

1) Annual report 2014, pg. 37

<https://www.ctgb.nl/documenten/jaarverslagen/2014/jaarrekening-en-jaarverslag/jaarverslag/ctgb-jaarverslag-2014>

2) Annual report 2015 pg. 40

<https://www.ctgb.nl/documenten/jaarverslagen/2015/begroting-en-werkplan-2015/jaarverslag/ctgb-jaarverslag-2015>

3) Annual report 2016 pg. 41

<https://www.ctgb.nl/documenten/jaarverslagen/2016/jaarverslag-2016/jaarverslag-2016/jaarverslag-2016/https://english.ctgb.nl/documents/annual-reports/2017/05/03/annual-report-2016>

4) Annual report 2017

Table 2. Number of appeals and their outcome

Year	Appeals	Won	Lost	Ended before verdict
2014	8	1	0	3
2015	5	1	0	2
2016	9	0	0	3
2017	8	1	0	2

Objections arise both from industry and NGOs. All such issues are managed by an advisory commission, which is comprised of external experts only. The Ctgb must obviously adhere to Court decisions; it presents and defends its assessments in court with the help of a well trained legal team. The IVC encourages Ctgb to continue proceeding on its path of independence from the pressures and requests of different stakeholders.

The balance between confidentiality/data protection on the one hand and openness and transparency on the other is fundamental, since both are key values underpinning Risk Assessment and Risk Management respectively. Industry tends towards increased confidentiality and protection of data, backed up by fairness of competition and the enterprise's right to defend its own invention. From the various NGO's there is pressure for increased transparency and free access to all studies relevant to risk assessment with the aim to minimize human and environmental health risks. The most demonstrative example of stakeholders clashing on where to put the line is the case about the environmental risks of neonicotinoids. The dispute centers around the arguments for refusing access by the industry to the requested information about possible adverse environmental effects as requested by NGO's (see Annex 13).

The mission of the Ctgb is to carry out and take ownership of the expert, science-based assessment of plant protection products and biocides; in doing so it contributes to the responsible use of plant protection products and biocides in Europe for humans, animals and the environment. The Ctgb's risk assessments and decisions are independent and transparent. They are established within legal frameworks and are based on scientific findings. In line with this mission the IVC appreciates that the Ctgb has supported the Court by identifying information relevant to assessing potential risks for the environment. The IVC suggests that for scientific authorities transparency should be the key value, however confidentiality/data protection should also be considered. The IVC is aware that developing a balanced approach between confidentiality and transparency is an ongoing process involving the whole EU regulatory framework. The IVC considers that scientific authorities are important stakeholders in these processes; in particular the Ctgb could contribute valuable practical experiences and viewpoints to support the evolution of legislation, at national as well as the wider EU level.

Both the legal team and the IVC agree on the need for further training and professional development; this would allow the Ctgb to go to court without requiring external support. Ctgb allows the legal team to participate in training courses, but it is challenging to find the time for professional training, due to current workload and deadlines.

Participation to the EU regulatory process of PPP and BP

The Ctgb participates in the EU process for approval of active substances. This process includes an extensive peer review process, where other MS review the work performed by the rapporteur member state. The IVC notes that the equally important commenting activity of Ctgb with regard to assessments carried out by other MS is more difficult to retrieve compared to the activity of Ctgb as RMS.

Under the Dutch presidency of the central zone Steering Committee in 2014, the Forum of directors of the central zone national authorities was established at the initiative of the Netherlands. The IVC commends this initiative and recognizes that the Ctgb has initiated an important, even though sometimes difficult, platform to discuss and solve longstanding issues for harmonization in the field of PPP regulation. In the same period, Ctgb has similarly contributed a significant effort to harmonize approaches for biocides within the ECHA-organized directors meeting for European Competent Authorities. Important topics include product applications for which no emission scenarios exist and evaluation of anti-fouling paints. The IVC considers that both the Ctgb actions to establish forums of directors of PPP and BP are valuable steps forward to establish and strengthen the EU regulatory scenarios.

Taking note of these achievements, the IVC recognizes that budget for participation to guidance development at EU or OECD level comes from the relevant ministries, and as such is diminishing every year. The resources currently available to Ctgb are mainly devoted to the everyday task of assessing substances and products. The IVC, therefore, encourages the Ctgb to present and support its request for further resources stressing the importance of a strong and proactive Ctgb role in the international regulatory scenarios.

Recommendations

Recommendations

Board and Management

Apart from being the final decision-making body in the process of authorisation of PPPs and biocides, the Board is also the figurehead of the organisation. This function means not just being the face of the Ctgb but rather being the custodian of the basic values of the organisation, i.e. collegiality, fairness, trust and opportunities. The IVC indeed experienced the pleasant atmosphere among the staff on the work floor in general but it missed a certain dynamic between the Board and the staff which it expected from the Board. For example, the Board could consider introducing as a routine at the end (or during lunch) of its monthly meetings an informal presentation of a staff member on his/her activities, achievements, suggestions and/or possible frustrations or even complete happiness. This way, the Board would start to acquaint with staff it hardly speaks with, or even sees.

Another general observation is an apparent low level of interest of the human resources management in the personal situation of staff members, despite the yearly personal conversation and personalised workplan. This can be illustrated by the seemingly disinterest in declarations of interest which are now largely interpreted as bureaucratic, unnecessary time spent rather than value some insight in the interests of staff. Like with the Board, the IVC members miss the dynamics of sharing personal interest. Similarly, the absolutely inadequately completed CVs speak for themselves: rather than being the showcase of the scientist's achievements, they are seen by many staff as a nuisance. The IVC considers the bonus system as an interesting, yet largely symbolic alternative for recognition of excellent performance. Making this process transparent by defining selection criteria and voting rights for all colleagues is likely to increase the staff's interest in this system, the more so when an independent individual (e.g. a retired staff member) makes the decisions based on the set criteria.

Recommendations

- The IVC encourages both the Board and the Management to promote close and regular interactions between the Board and the scientific assessors; this will further support the scientific consistency and robustness of the evaluation process.
- Furthermore, the IVC strongly recommends that efforts be made, in particular by the Board and Human Resources management, to change the

culture from disinterest into one where personal achievement is appreciated, where scientists are proud of their role of assessing potential risks of biocides and PPPs, of their level of expertise and experience. Organising monthly so-called "brown-back" lunches where one team shares its most interesting issues and experiences with colleagues in a very informal way could be a useful start.

- The IVC recommends upgrading of the bonus award system by making it fully transparent (maybe apart from the voting as such), adding other non-financial awards, as appropriate, and to include all science staff.
- Furthermore, the IVC recommends that ecotoxicology staff members and other eligible candidates of scientific staff who have not yet done so apply for ERT recognition since it recognizes the excellence and expertise of its members and increases the international reputation of Ctgb and its scientific staff.

Openness and transparency

Ctgb is the Dutch National Authority and a strong and aspiring regulatory force in Europe. Whilst considerable progress has been made since 2013, the IVC believes that Ctgb could be more open and transparent as a common theme running throughout the organisation. This would better help to distinguish between the fundamentally important risk assessment and subsequent risk management decisions, it would enhance communication with peers and the wider society and could be seen to promote greater public trust.

Furthermore, recognising the primary need to communicate with Dutch stakeholders as well as the general policy of the Netherlands to protect the national language, the translation into English of relevant publicly available documents, such as the Authorisation decision of the Board, will increase the transparency with the wider public community and other Competent Authorities of EU Member States and beyond.

Recommendations

To this end, the IVC recommends that:

- In line with the conceptual framework to distinguish risk assessment from risk management (for example, in the EU Regulation /EC/178/2002 of the European

Parliament and of the Council of 28 January 2002) an appropriate level of openness and transparency throughout the work processes within Ctgb is the only solution to provide the necessary insight of potential or actual blurring of scientific risk conclusions by risk management arguments. This could be achieved by formally appointing a senior responsible representative of the science department as Chief Scientific Officer (CSO), and non-voting attendant and advisor to the Board during its decision-making discussions.

- Minutes of decision making meetings should provide sufficient details of discussions to permit distinctiveness in recognizing management from scientific arguments. Specifically, the IVC recommends that the Board minutes and records of their discussions should include the clear identification of changes introduced by the Board in the scientific assessment reports submitted to the Board for discussion and consideration.
- Recognizing the importance of Ctgb participation to the EU peer-reviewing process, accurate and transparent (and easily retrievable) records of comments and exchanges regarding all DARs, dRARs and CARs should be kept in the comprehensive DMS.

Scientific output and outreach

The overall view of the IVC is that the scientific output and outreach of the Ctgb is of high scientific quality in general. The risk assessments and decisions reviewed are conducted effectively, with high level scientific knowledge, a sound use of up-to-date guidances, and appropriate documentation. In general, there is evidence of internal peer review of the Dossiers within the Ctgb and the Board, although in some cases the peer review appeared rather cursory or limited. Involving the Board in the peer review process of all dossiers is endorsed by the IVC as good practice and should be continued.

The IVC considers openness and transparency as basic values of European societies. In general, by distinguishing the scientific risk assessment and risk management processes and proactively communicating about their outcomes, by the Ctgb would contribute to building public trust. Therefore the IVC concludes that both the scientific

quality of processes deployed and the perception of the quality achieved would still be further enhanced by the following recommendations.

Recommendations

- In cases where the Ctgb interpretation of guidance documents is challenged during the peer-reviewing process, the IVC recommends a consistent and transparent policy for a feed-back discussion of the outcomes of peer-reviewing with the relevant Unit, including full records of meetings, discussions and conclusions, and preferably with the official involvement by at least one Board representative.
- The IVC commends the Ctgb for its proactive international initiatives and achievements in recent years and encourages the Ctgb to present and support its request for further resources stressing the importance of a strong and proactive Ctgb role in the international regulatory scenarios. Specifically, the IVC reiterates its earlier recommendation in 2013 about the importance for Ctgb to be actively involved at the OECD level with on-going arrangements for the global review of active substances using work-sharing arrangements.
- The IVC encourages the Ctgb to ensure that at least one staff member should have specialized training in human exposure assessment (non-dietary as well as dietary). This could help the Ctgb to deal with difficult/controversial issues concerning both PPP and BP.
- The IVC strongly recommends to minimize the outsourcing of external risk assessment evaluations, limiting it to exceptional circumstances and then only to public-funded institutes or universities, having assessed their potential funding conflict and with due regard to confidentiality.

Overall Conclusions

The IVC was very pleased with the assistance provided by the staff in helping to find the necessary information the Committee wished to evaluate. During the IVC visit, the team has achieved a clear and comprehensive understanding of the current Ctgb structure and functioning with access to adequately detailed information. This unimpeded allowance to review all science-related information, signalled self-confidence with respect to the scientific approach and output of the organisation. Considering the time frame constraint and the impossibility to thoroughly review all dossiers produced since 2013, the IVC concluded that the Ctgb operates at an excellent scientific level. Its scientific output is of high quality, both with respect to providing the Board with a solid basis for its decision making on the authorization of plant protection products and biocides, but also in its international contributions to risk assessment. An efficient science management system along with timely implemented internal procedures have distinguished the Ctgb by facilitating its adaptation to the changes in EU complex legislation.

The IVC was pleased with the active contribution of the Ctgb to authorizing and releasing biological and low-risk pesticides on the market and considers this to be highly valuable. As one of the front runners in Europe, the Ctgb thus promotes the conditions of organic farming. The initiative of the Ctgb to establish a directors' Forum for the central Europe zone has also been a positive and timely strategic move towards further harmonization and increased efficiency.

However, the IVC also noted that the Board and senior management have maintained their policy of confidentiality where possible and misinterpreting a Dutch law on the protection of personal privacy as a must, rather than conditional. The IVC strongly believes that to be trusted, one should be open and honest. Without a policy of transparency wherever possible, the IVC anticipates that the Ctgb may in time become isolated among its peers at the international level. Also worse, based on another Dutch (and European) law, anyone including NGO,s can demand access to information at any time about any Ctgb expert, today finding out there is hardly any such information.

Acknowledgement

The members of the IVC acknowledge the support and assistance offered by all staff members we came across and would like to thank them all for their patience and willingness to spend their precious time with us for interviews or technical help. In particular the IVC would like to thank Ir. Johan de Leeuw, Chairman of the Board, the members of the Board, and Dr. Ir. Luuk van Duijn, Director, for their trust in the capacity, capability and expertise of the IVC membership. We hope we did not totally surprise you with our findings.

Not surprisingly, Dr Sjon Kortekaas has been our beacon when some of us got lost in the sea of documents, always patient and tireless. Thank you, Sjon! And thank you, Eva Solinger not only for making our live easier by taking care of our travel arrangements, but also for your assistance in February when airports were closed and one of us needed health-related support.

Statement Of Commitment

Dr. Herman Koeter, Belgium (chairman)



Dr. Sari Autio, Finland



Dr. Mar Carretero, Spain



Prof. Anthony Richard Hardy, United Kingdom



Dr. Alberto Mantovani, Italy



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Terms of Reference - Visitation Ctgb 2018

Objective and scope of the international visitation

1. The requirements imposed on competent authorities by the European Commission, the industry and general public are challenging. Competent authorities are criticized for noncompliance with legal deadlines and inefficiencies in the evaluation and decision-making procedures. 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 goal 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. To that end, suggestions and advice will be given on possible improvements of aspects of the scientific decision-making process and or decision content which are considered essential for ensuring timely independent and high quality outputs of the Ctgb.
2. 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:
 - o Quality: the overall scientific and technical quality of the risk assessments advisory documents that are prepared by the secretariat to substantiate the subsequent formal Decisions by the Board,
 - o 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'
 - o Board: the contribution and role of the Board in the decision making process, in particular the level of competence and procedural aspects.
 - o Existing authorizations and possible actualization with a view to developments in EU legislation
 - o Progression in new scientific developments.
 - Dealing with satisfying all stakeholders (European Commission, Regulatory Authorities of other Member States, industry, general public) and apparently contradictory requirements, considering:
 - o The requirements, procedure and timeframes for product authorisation are set out in the biocides ((EU) 528/2012) and the plant protection products regulation ((EC) No 1107/2009);
 - o The need for transparency and the existing rules for disclosure ;
 - o In addition to their primary tasks (product evaluation and authorisation), competent authorities are held responsible for fostering the authorisation of green products and stimulating the transition to integrated pest management and sustainable farming systems.
 - o A harmonised framework of scientific decision-making as a prerequisite for improving the efficiency of the evaluation and decision-making procedures. Resolving issues among member states for a harmonised framework takes time in the short run.
 - o Strong emphasis on timeliness leads to a tendency to prioritise higher tier assessments of the core dossier and leaves the diverging views to be solved on an individual basis during product authorisation (in the national addenda). Individual solutions on diverging views among MS's hamper mutual recognition, and diminishes reliance, and opportunities for co-operation and work-sharing among MS's.

3. The IVC is requested to make recommendations as it deems appropriate.
 - Indicators are i.a.:
 - o Resources:
 - Extent of available evaluative capacity;
 - mammalian and environmental toxicology,
 - metabolism in plants animals and soils,
 - residual traces in food and feed,
 - fate and behaviour in the environment
 - product performance project management
 - o Quality:
 - Level of expertise and experience of staff and the Board;
 - Scientific/technical quality of the advisory documents as prepared for the Board;
 - o Process:
 - Documentation and transparency of the advisory and decision-making processes;
 - In-house management structure and responsibility levels, consultation and checks and collegial feedbacks;
 - o The Board:
 - Assessment by the Board of the advisory documents prepared by the secretariat. Interaction of the board and secretariat. Indicators of independence and absence of bias in the decision making process and outcome
 - o External Constraints:
 - Legal
 - Procedural
 - Practical

The International Visitation Committee (IVC)

4. 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 after consultation with the Board by Herman Koëter (CV attached) who will also chair the Committee.

Procedure

5. The IVC members will be given unlimited access to all documents. Where relevant, the committee is free to speak with people outside the 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.
6. 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.

The remuneration of the members of the IVC will be €600 per working day of 8 hours; this includes meeting days as well as days working from home or office. Travel expenses (economy class) will be reimbursed following submission of receipts.

Timetable

7. Based on the request of Ctgb to receive the committee's final report before summer 2018, the IVC considered whether it would realistically doable to meet that request and concluded that such a deadline could affect the quality of the project. The following timetable is proposed with the provisos that:
 - that agreement of the Terms of Reference will be achieved in November 2017
 - the international visitation committee (IVC) can be established in November 2017;
 - that all existing documents on protocols, procedures, criteria, internal compliance monitoring and other issues relevant for the IVC, where possible, are available or translated in English, will be made available to the IVC by mid March 2018
8. The committee is provisionally scheduled to meet on 4 occasions 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
November 2017	Agreement on Terms of Reference (ToR) and the members of the committee
31 January 2018	First meeting of the international visitation committee discussing the Activity plan, strategy, tasks and timing
28 February 2018	Approval of the Activity plan by the Board. Activity plan indicates methodology and approach for the evaluation, including research questions and indicators. List of all dossiers as of 2013. Access to selected dossiers/documents for review; list of IVC questions
Mid March 2018	List of questions; In-house discussions within the Ctgb about possible internal actions in preparation for the visitation, largely based on the set of questions considered by the IVC
Late March 2018	(virtual) Meeting of the IVC members: discuss progress, reviewing responses received from Ctgb, first impressions, assessment approaches, practicalities
May 2018	Visitation mission (probably 2 days), interviews with Ctgb personnel & the Board. At the end of day 2, the IVC will communicate an overview of its provisional findings with the Ctgb management.
August 2018	Delivery draft report , followed by Meeting of the Visitation Committee with the Ctgb management to discuss the draft final report.
26 September 2018	Formal presentation of the Final Visitation Report

Date 22-11-2017.

Dhr. Dr. H.B.W. M. Koeter

Dhr. Ir. J.F. de Leeuw



Europass Curriculum Vitae



Personal information

First name(s) / Surname(s)

Address(es)

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Herman B.W.M. Koeter

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Netherlands

1 October 1947

Male

Work experience

Dates

January 2009 - ongoing

Occupation or position held
Main activities and responsibilities

Founder and Managing Director, Orange House Partnership (OHP)

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) animal health and welfare (iii) the Globally Harmonised System for Classification and Labelling of chemical substances and mixtures (GHS, CLP), (iv) safety assessment of food and food ingredients/contaminants, (v), food-borne diseases, biological hazards, (vi) compliance monitoring, and (vii) 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 and animal welfare issues, as example: providing the Ministry of Environment in South Africa on the risk management of chemical wastes; advising the Directors General of 6 Ministries in The Netherlands on a long-term strategy for better science with less animals; advising the Swish Government on animal-free dermal risk assessment approaches.
- 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 in the areas of good agricultural practices, animal husbandry, health and welfare, 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 provided high level policy and strategic advice on all issues related to the mission of the Authority. Emphasis was on science policy and interplay between the Commission, EU Member States, NGO's and other stakeholders and the Authority. I provided guidance on scientific approaches to the Heads of Science Units and Technical Support Units and ensured that animal welfare remained high on the agenda of EFSA. Furthermore, I advised on defining new scientific projects and, as needed, provide the terms of reference for these projects. I replaced the Executive Director as appropriate and expanded and maintained 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.

Name and address of employer In this position I managed only a small staff of personal assistants.
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.

Name and address of employer 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).
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)**

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.

Name and address of employer 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.
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
Main activities and responsibilities

Principal Administrator, Environment, Health and Safety Division, OECD

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 at the Netherlands Organisation for Applied Scientific Research - TNO:

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

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)

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)
 Other language(s)
 Self-assessment
 European level (*)

Dutch

	Understanding				Speaking				Writing	
	Listening		Reading		Spoken interaction		Spoken production			
English	C 2	Proficient user	C 2	Proficient user	C 2	Proficient user	C 2	Proficient user	C 2	Proficient user
German	B 2	Independent user	B 2	Independent user	B 1	Independent user	B 1	Independent user	A 2	Basic user
French	B 2	Independent user	B 2	Independent user	B 1	Independent user	B 1	Independent user	A 2	Basic user
South African	B 1	Independent user	B 1	Independent user	A 1	Basic user	A 1	Basic user	A 1	Basic user

Italian

A	Basic user	A	Basic user	A	Very basic user	A	Very basic user	-	No knowledge
1		1		1		1			

(*) 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 acting as 'St.Nicolas' in kindergardens 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 was the Co-Chair of the 7th and 8th World Congresses on the Use of Animals and Alternatives in the Life Sciences (Rome, August 2009, 1000 participants, budget: €1.0 Million; and Montreal 2011, 900 participants, budget: close to €1.0 million). I was member of the organising committee of all previous World Congresses on the use of animals. Since April 2013 I am the President of the Alternatives Congress Trust (ACT) under whose auspices the World Congresses are organized.

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.

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, Scissor Sisters, Marylou Harris 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:

- Chairman of the Netherlands National Committee for the Protection of Animals Used or Scientific Purposes (2014 ongoing)
- Editorial Board of the scientific journal ATLA (1993 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 President of the Alternatives Congresses Trust (ACT) (2008 ongoing) (President since 2013)

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

- Dutch government advisory council on animal studies (1988 – 2009)
- 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: **FIRST TWO PAGES OF THE MOST RECENT PUBLICATIONS OUT OF A TOTAL OF MORE THAN 100**

- Schiffelers, M.J.W.A., Blaauboer, B.J., Bakker, W.E., Beken, S., Hendriksen, C.F.M., **Koëter, H.B.W.M.**, Krul, C., 2014. Regulatory acceptance and use of 3R models for pharmaceuticals and chemicals: Expert opinions on the state of affairs and the way forward. *Regul. Toxicol. Pharmacol.* 69, 41-48
- Koëter H B W M**, Autio, S., Banasiak U., Lynch M., and Silano V., (2013). 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. 5 July 2013, CTGB..
- 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.
- Hartung T and **Koëter H.B.W.M.** (2008). Food for thought on food safety testing. *ALTEX* 25: 259-265
- Cooper R.L., Lamb J.C., Barlow S.M., Bentley K, Brady A.M., Doerrer N.G., Eisenbrandt D.L., Fenner-Crisp P.A., Hines R.N., Irvine L.F.H., Kimmel C.A., **Koëter H.B.W.M.**, Li A.A. and Makris S.L. (2006). A tiered approach to life stage testing for agricultural chemical safety testing. *Clinical Reviews in Toxicology* 36: 69-98.
- Koëter H.B.W.M.** (2005). The European Food Safety Authority's scientific activities: Harmonization of food and feed risk assessment approaches across Europe. In : Parma e la chimica, opportunità professionali. Ordine dei Chimici della Provincia di Parma. p. 109-117.
- Koëter H.B.W.M.** (2003). Mutual acceptance of data : harmonized test methods and quality assurance of data; the process explained. *Tox. Letters* 140/141: 11-20.
- Owens W. and **Koëter H.B.W.M.** (2003). The OECD programme to validate the rat uterotrophic bioassay: An overview. *Env. Hlth. Persp.* 111: 1527-1529.
- Koëter H.B.W.M.** (2002). Dialogue and collaboration: a personal view on laboratory animal welfare developments in general, and on ECVAM's first decade in particular. *ATLA* 30 (Supplement): 207-210.
- Barlow S.M., Greig J.B., Bridges J.W., Carere A., Carpy A.J.M., Galli C.L., Kleiner J., Knudsen I., **Koëter H.B.W.M.**, Levy L.S., Madsen C., Mayer S., Narbonne J.F., Pfannenkuch F., Pordanchuk M.G., Smith M.R. and Steinberg P. (2002). Hazard identification by methods of animal-based toxicology. *Fd. Chem. Tox* 40: 145-191.
- Koëter H.B.W.M.** and Visser R. (2002). Work in OECD on Chemical Safety: Approaches for Human Risk Assessment. *Industrial Health* 38: 109-119.
- Koëter H.B.W.M.** and Goldberg A.M. (2000). The OECD guidance document on humane endpoints for experimental animals used in safety evaluation studies. In: *Progress in the Reduction, Refinement and Replacement of Animal Experimentation.* p. 891-896. Eds. M. Balls, A.M. van Zeller and M.E. Halder. Elsevier Science BV, Amsterdam, The Netherlands.
- Griffin G. and **Koëter H.B.W.M.** (2000). Update on refinement guidelines. In: *Progress in the Reduction, Refinement and Replacement of Animal Experimentation.* p. 1693-1696. Eds. M. Balls, A.M. van Zeller and M.E. Halder. Elsevier Science BV, Amsterdam, The Netherlands.
- Koëter H.B.W.M.** (1998). The OECD Test Guidelines Programme and animal welfare concern: how to avoid major animal suffering. In: *Humane Endpoints in Animal Experiments for Biomedical Research.* p. 13-14. Eds. C.F.M. Hendriksen and D.B. Morton. The Royal Society of Medicine Press Ltd., London.

- Tichias K., Fentem J., Basketter D., Botham P., Brooker P., Brunner L., Evans P., Fairhurst S., Fassold E., Fielder R., Gerberick F., Harvey P., **Koëter H.B.W.M.**, Parsons P., Schlede E., Shannon D. and Spielmann H. (1998). Progress in toxicological testing : reduction and refinement issues. Recommendations from a joint UK Government / ECVAM meeting. *ATLA* **26**: 619-627.
- Koëter H.B.W.M.** (1997). Testing and risk assessment strategies: International perspectives. *Reprod. Toxicol.* **11**: 453-456.
- Koëter H.B.W.M.** (1996). Reproductive hazard assessment of chemical exposure at the workplace. In: *Current topics in occupational health : knowledge and research needs* – p. 105-112. Eds. O. Svane, T.C. Aw and V.H. Madsen. European Commission DG V Health and safety Series, Luxembourg.
- Koëter H.B.W.M.** (1996). Validation: a highly charged concept. *Toxicology In Vitro* **9**: 851-856.
- Koëter H.B.W.M.** (1996). International harmonization of test methods for hazard characterisation taking into account animal welfare issues. In: *Proceedings of the ICLAS / CSIS Working Group Meeting on Complementary Methods*. ISBN: 84-605-4232-7.
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- Koëter H.B.W.M.** (1996). *In vitro* toxicity models will answer the terms and criteria of (inter)national regulatory agencies: an international opinion. *Human Exp. Toxicol.* **15**: 929.
- Koëter H.B.W.M.** (1995). International harmonisation of immunotoxicity testing. *Human Experimental Toxicology* **14**: 151-154.
- Koëter H.B.W.M.** (1994). The science and the art of regulatory toxicology : How to deal with alternative tests. In: *Proceedings of the Symposium Current Trends: In Vitro Skin Toxicology and Eye Irritancy Testing*, April 21-23, 1993, Ottawa – p. 15-22. ISBN: 0-9698111-0-1.
- Van Looy H.M. and **Koëter H.B.W.M.** (1994). The OECD and international regulatory acceptance of the three R's. In : *Alternatives to Animal testing; New ways in the Biomedical Sciences, Trends and Progress* – p. 13-19. Ed. C.A. Reinhardt. VCH, Weinheim, Switzerland.
- Koëter H.B.W.M.** (1994). What can be expected from *in vitro* methods. In: *In Vitro Skin Toxicology; Irritation, Photoirritation, Sensitization* – p. 385-392. Eds. A. Rougier, A.M. Goldberg, and H.I. Maibach. Mary Ann Liebert, Inc., New York, USA.
- Koëter H.B.W.M.** (1994). Inhalation Toxicology: Current approaches and administrative needs. In: *Respiratory Toxicology and Risk Assessments* – p. 27-36. Eds. P.G. Jenkins, D. Kayser, H. Muhle, G. Rosner, and E.M. Smith Wissenschaftliche Verlagsgesellschaft mbH Stuttgart, Germany.
- Koëter H.B.W.M.** (1994). Principles for a pragmatic approach to the regulatory acceptance of alternative tests. *Toxicology In Vitro* **8**: 925-930
- van de Sandt J.J., Rutten A.A.J.J.L. and **Koëter H.B.W.M.** (1993). Cutaneous toxicity testing in organ culture: neutral red uptake and reduction of tetrazolium salt (MTT). *Toxicology In Vitro* **7**: 81-86.
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- Koëter H.B.W.M.** (1993). Test guideline development and animal welfare: regulatory acceptance of *in vitro* studies. *Reprod. Toxicol.* **7**: 117-123.
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Europass Curriculum Vitae



Personal information

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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	<ul style="list-style-type: none">• 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 <i>ad hoc</i> 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 4 detailed 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

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 Institute (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

Personal skills and competences

Mother tongue(s) **English**

Other language(s)

Self-assessment

European level ()*

Irish

Understanding

Listening

Reading

Speaking

Spoken
interaction

Spoken
production

Writing

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 pesticides.

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

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, university students)
6. **Contact details:**

Office: Finnish Organic Research Institute,
Natural Resources Institute Finland (Luke)
Latokartanonkaari 9, 00790 Helsinki, Finland.
Mobile tel. +358 29 532 2110
e-mail sari.autio@luke.fi

Home: Etelärinteentie 44, 10300 Karjaa, Finland.
Personal mobile tel. +358 50 539 4044

7. **Education:**

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Institution [Date from - Date to]	Degree(s) or Diploma(s) obtained:
University of Helsinki Faculty of Biological and Environmental Sciences Department of Environmental Sciences 12/2013 – 3/2017	Doctor of Philosophy, Environmental Science
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 (2 nd official language)	4	4	4
English	4	4	4
German	3	3	3
Russian	1	1	1
Estonian	starting phase	starting phase	starting phase

9. Memberships of professional bodies and working groups:

Member of the Finnish Society of Environmental Sciences.

Member of the council of the trade union for natural, environmental and forestry scientists Loimu (2017 – 2020).

Steering group for the Finnish National Action Plan on the sustainable use of plant protection products (2011-)

Steering group member in several research projects concerning the environmental effects of plant protection products (PesticideLife, GlyFos I and II, Neomehi).

Participant in the OECD expert group on pesticide risk indicators (EGPRI).

Kevake working group for reorganising the chemicals product surveillance tasks from three separate authorities to Finnish Safety and Chemicals Agency Tukes (2010). The new organisation started in 2011.

10. Other skills:

Project management skills. Normal computer skills (including normal Microsoft Office programs like Word, Excel, Powerpoint, Outlook, OneNote etc.), internal IT-Examination within the Finnish Environment Institute. Experience on using the FOCUS models and scenarios for ground water and surface water risk assessment of plant protection products. Interest in environmental risk indicators

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of chemicals, e.g. the HAIR 2010, and in Multiple Criteria Decision Analysis methods. Qualitative analysis methods.

11. Present position:

Research Manager, Finnish Organic Research Institute, 1.6.2017- 31.12.2020.

Currently on the leave of absent from my permanent position as Senior Adviser at the Finnish Safety and Chemicals Agency Tukes, Plant Protection Products Unit.

12. Key qualifications:

In my current position as research manager I am responsible for coordinating the researchers' network on organic farming in Finland. The Finnish Organic Research Institute (FORI) is a multidisciplinary research organisation operating under the University of Helsinki and the Natural Resources Institute Finland (Luke). FORI promotes organic food production and consumption throughout the Finnish food chain by the means of research, science communication, education and development projects on its four pillars of research: primary production, the environment, organic foods and the society. My tasks include also helping the researchers to seek and apply for funding for their research projects. National editor for Organic Eprints (<http://orgprints.org/>).

I have almost 30 years of experience in environmental fate and ecotoxicological risk assessments of plant protection products, including the EU risk assessments of the active substances for which Finland is the Rapporteur Member State, and defending the evaluations of those active substances at the EFSA PRAPeR expert groups. I was also involved with the international cooperation in the decision making within the DG SANCO Standing Committee on Food Chain and Animal Health, for peer review of risk assessments prepared by other MS, OECD Pesticides WG including the expert group on pesticide risk indicators (EGPRI), and Nordic pesticide co-operation under the Nordic Chemicals Group financed by the Nordic Council of Ministers, and other administrative tasks concerning the authorization of plant protection products both at national and international level. I have about five years of experience on leading the PPP-team within the FEI, and two years of experience as project coordinator within the Pilot project on Biocides funded by the Commission DG ENV.

In 2012 I was chairing the Northern Zonal Steering Committee for evaluation of PPP, and in 2013 I was supporting the Latvian chairperson as co-chair. The zonal steering committee manages the workload between the member states to share the evaluations of plant protection products within the three zones of the EU. The Northern zone is represented in the Inter-zonal Steering Committee by its chairperson and co-chair. In this position I was also responsible for coordinating the update of the Guidance Document on work-sharing in the Northern zone in the registration of plant protection products. The Northern Zone Guidance Document

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is a living document and the latest version of it can be found at: <http://www.tukes.fi/Tiedostot/Kemikaalituotteet/kasvinsuojeluaineet/ohjeet/Northern zone GD 2016 version5.0.pdf>

During the preparation of the EU regulation of plant protection products, the framework directive on the sustainable use of pesticides and the pesticide statistics regulation, I was involved in the negotiations in the Council working group (2006-2009). Consequently, I also participated in the preparation of the National Action Plan (NAP) on the sustainable use of Plant Protection Products in Finland, and currently participate in the implementation of it.

The motivation for my doctoral studies arised from the experience on preparing and implementing the Finnish NAP, and Tukes granted me two years study leave to prepare tools for evaluating the Finnish NAP in 2014-2015. My PhD thesis "Do we listen to earthworms? Tools for evaluating the Finnish National Action Plan on the sustainable use of plant protection products" was published in 2016 in the Tukes Publications Series and is available at: <http://www.tukes.fi/Tiedostot/julkaisut/Autio Do we listen to Earthworms.pdf>.

I also participated the PesticideLife project partly funded by EU LIFE+ in 2010-2013. The aim of the project was 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.

Furthermore, during my career I have participated as steering group member to supervise several research projects concerning the fate and behaviour and effects of plant protection products in the Northern climatic conditions, the most recent projects being Neomehi (2013-2015, about the impact of neonicotinoid insecticides on honeybees), GlyFos I (2013-2016) and GlyFos II (2016-2018, about the behaviour of glyphosate in soils and to find alternatives for glyphosate uses). Currently I am also supervising an undergraduate student in her Master's degree study to evaluate the applicability and effectiveness of different environmental risk mitigation options for plant protection products.

In 2013 I was invited to the international visitation committee for evaluating the scientific process, the scientific output and the decision-making process of the Netherlands Board for the Authorisation of Plant Protection Products and Biocides (CTGB). The visitation committee comprised of five senior colleagues having expertise on the risk assessment of plant protection products and biocides from different European Member States. In 2017 Tukes conducted an internal evaluation of its risk assessment processes of plant protection products and biocides, for which I was nominated to collect and provide information for the evaluators on the basis of the Dutch experience.

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13. Professional experience

Date from - Date to	Location	Institute	Position	Description
6/2017 – the current contract is until 31.12.2020	Helsinki	Finnish Organic Research Institute (FORI)/ Natural Resources Institute Finland (Luke)	Research Manager	Coordinating the multidisciplinary researchers' network on organic farming in Finland; promoting the research of organic food production and consumption throughout the Finnish food chain; science communication; participating in education and development projects; helping the researchers to seek and apply for funding for organic research.
1/2011 - 5/2017 (including the study leave for doctoral studies in 2014-2015)	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.
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

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14. Personal interests:

Organic home gardening, literature, nature. I live in countryside in the neighborhood of farmers, where I can follow the annual rhythm of everyday farming practices on adjacent fields. I also appreciate that my children have had an opportunity to see where the food comes from and go to school in a small country village. Since my children have grown up and moved from home, I am volunteering for the benefit of childrens' welfare via Mannerheim League for Child Welfare. Currently I participate in its "Friend for an Immigrant Mum" –activities.

15. Publications:

Autio, S., Iivonen, S. & Herzon, I. 2017. Luomutuotannon eduista on tutkimustietoa. Reply published in Helsingin Sanomat on 5.8.2017.

Autio, S. & Iivonen, S. 2017. Organic agriculture in Finland. Poster presented at the NJF Seminar 495 - 4th Organic Conference: Organics for tomorrow's food systems, 19 - 21 June 2017, Mikkeli, Finland.

Autio, S. 2016. Do we listen to earthworms? Tools for evaluating the Finnish National Action Plan on the sustainable use of plant protection products. Academic dissertation. Finnish Safety and Chemicals Agency Tukes Publication series vol. 2/2016. 287 pages.
http://www.tukes.fi/Tiedostot/julkaisut/Autio_Do_we_listen_to_Earthworms.pdf

Räsänen, K., Nousiainen, R., Autio, S., Kurppa, S., Junnila, S., Tiilikkala, K., Jauhiainen, L., Rämö, S. & Lemola, R. 2013. A synthesis report on implementation of IPM and demonstrating the aquatic risks of plant protection products on a Nordic-Baltic scale. PesticideLife project Action 4, MTT Agrifood Research Finland, NSL Nylands Svenska Lantbrukssällskap and Finnish Safety and Chemicals Agency Tukes. 29.11.2013. 42 pages.
<https://portal.mtt.fi/portal/page/portal/mtt/hankkeet/pesticidelife/julkaisut/PELI%20ty%C3%B6paketti%204%20task%203%20ja%20liitteet.pdf>

Mäkinen, Taina; Autio, Sari; Erlund, Patrik; Junnila, Sanni; Laitinen, Pauliina; Markkula, Irmeli; Räsänen, Kati; Tiilikkala, Kari 2013. Poliittikkakatsaus kasvinsuojeluaineiden kestävästä käytöstä : päivitetty 30.9.2013. MTT Raportti 20. 41 p. <http://urn.fi/URN:ISBN:978-952-487-483-0>

Autio, S. 2013. Kasvinsuojeluaineiden ympäristöriskien hallinta. Kasvinsuojelulehti 2/2013. S. 40-42.

Koëter, H., Autio, S., Banasiak, U., Lynch, M., Silano, V. & Cuvillier, A. 2013. Report on the international visitation of the Netherlands Board for the Authorisation of Plant Protection Products and Biocides (CTGB) addressing the scientific process, the scientific output and the decision-making process. 5.7.2013.

Alanko, A-M., Autio, S., Huusela-Veistola, E., Jalli, H., Jalli, M., Junnila, S., Markkula, I., Mäkinen, T., Räsänen, K. & Tiilikkala, K. 2013. Integroitu kasvinsuojelu (IPM) ja riskienhallinta viljanviljelyssä. PesticideLife projekti (21090039). MTT Raportti 107. ISBN 978-952-487-467-0. 48 pages. <http://www.mtt.fi/mttraportti/pdf/mttraportti107.pdf>

Räsänen, K., Nousiainen, R., Kurppa, S., Autio, S., Junnila, S., Tiilikkala, K., Kaseva, J. & Laitinen, P. 2013. How to measure the environmental risks from uses of plant protection products for achieving the IPM requirements and risk communication - A case study on the production chain of cereal farming in Finland. Comply 4 report: Vertical and horizontal and Nordic-Baltic implementation of the IPM actions, PesticideLife project (21090039). MTT Report 105. ISBN 978-952-487-465-6 (printed), ISBN 978-952-487-466-3 (web publication). 65 pages.
<http://www.mtt.fi/mttraportti/pdf/mttraportti105.pdf>

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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.

Laitinen, P., Junnila S., Markkula, I., Tiilikkala K., Autio S. ja Erlund, P. 2011. Poliittikkakatsaus 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/mtrraportti/pdf/mtrraportti20.pdf>

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.

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 & 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.

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

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

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.

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

Lodenius M. & Autio S. 1987. Elohoepa 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 järviökosysteemissä. 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.

Curriculum vitae

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

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.



Europass Curriculum Vitae



Personal information

First name(s) / Surname(s) **Maria Mar CARRETERO GOMEZ**
Address(es) Avda de Portugal, 23 Zip Code 28420, City: Galapagar, Country: Spain
Nationality Spanish
Date of birth 9 October 1965
Gender Female

Desired employment / Occupational field **Training Coordinator**

Work experience

Dates	2003 ongoing
Occupation or position held	Superior Technician in Public Health (Civil Servant)
Main activities and responsibilities	Description of the post: <ul style="list-style-type: none">• Management of the programme of official control and monitoring of annual monitoring control program Pesticides residues in food of animal and plant origin, Food Improvement Agents, Residues of veterinary medicines in food of animal origin, and Chemical contaminants in food.<ul style="list-style-type: none">○ Design of sampling strategy review of analytical methods and interpretation of results communications on rapid alert system in case of infringement.○ Sanction procedures.○ Follow-up, data collection report and evaluation.○ Data collection to EU information systems.• Draw up of documented procedures based on EFQM for competent authorities on Coordination of follow-up measures. Technical instructions and guidelines to inspectors based on EU legislation on food safety.• Reports on risks assessment, risks profiles, on chemical risks on food of animal and plant origin. Risk characterisation on non-compliant results to pesticides MRL's.• Direction and coordination of working groups on Chemicals, agenda, and minutes.• Legislation: follow-up, comments on proposals, rules for implementation and drafting proposals.• Continuous training to official inspectors on risk analysis, official control of additives contaminants, veterinary residues, and pesticides.• Relations with other administrations, consumers and business operators.• Assistance to Food Veterinary Office missions
Name and address of employer	Regional Authority of Madrid
Type of business or sector	Public health
Dates	23 rd -26 th January 2018
Occupation or position held	Tutor

Main activities and responsibilities	BTSF world EU-workshop on plant products, plant health, contaminants and microbiology. Lectures on Import Export conditions for agro food products to EU, Contaminants in food of non-animal origin, Official controls on contaminants, RASFF responding and follow- up notifications. Phnom Penn Cambodia
Name and address of employer	BTSF
Type of business or sector	Food safety
Dates	June 2017, July 2017, September 2017 and October 2017
Occupation or position held	Tutor and training Coordinator (Session4)
Main activities and responsibilities	BTSF Food Improvement Agents, Phase II Contract n° (EAHC) 2013 96 04. Lectures and practical sessions on application of Quantum Satis principle and on Design of Control Plans on Food Improvements Agents. Training Coordinator in session 4 held in Frankfurt October 2017. Drogheda/Ireland, Krakow/Poland, Frankfurt/Germany
Name and address of employer	BTSF
Type of business or sector	Food safety
Dates	February 2017
Occupation or position held	Expert
Main activities and responsibilities	62412_TAIEX Workshop on Official Controls and Measures to Monitor Residues in Live Animals and Animal Products Control Plans for imported products
Name and address of employer	EU-Commission TAIEX
Type of business or sector	Food safety
Dates	October 2016
Occupation or position held	Short term Expert
Main activities and responsibilities	SMMSS Project Support to Modernization of Mongolia's Standardization System EuropeAid/134305/C/SER/MN Activity Number:R2C12: Training on vaccination of contagious and infectious diseases of animal and registration and surveillance for quality and safety of vaccines. Requirements for imported veterinary medicines
Name and address of employer	EU-Mongolia
Type of business or sector	Food and veterinary safety
Dates	June 2016
Occupation or position held	Short Term Expert
Main activities and responsibilities	SMMSS Project Support to Modernization of Mongolia's Standardization System EuropeAid/134305/C/SER/MN Activity Number: R7A3b Training on specific product directives, including stakeholders, manufacturers, quality infrastructure, government, legislators (Training on food Additives Regulation 1333/2008/EC).
Name and address of employer	EU-Mongolia
Type of business or sector	Food and veterinary safety
Dates	April-June 2016
Occupation or position held	Short Term Expert
Main activities and responsibilities	Short Expert Local technical assistance to support SPS in Centroamerica (PRACAMS) Europe Aid/133406/D/SER/Multi. Training. Activity C1R1A1-21f. Five-week assistance to the implementation and harmonization of Regulation of Food Additives. Design of procedure to update the positive list of additives in Centralamerica Region. Including harmonization of rules for the Central American Custom's' Union. Guatemala
Name and address of employer	EU-PRACAMS
Type of business or sector	Food safety

Dates	May 2016
Occupation or position held	Short Term Expert
Main activities and responsibilities	Short Expert Local technical assistance to support SPS in Centro America (PRACAMS) EuropeAid/133406/D/SER/Multi. Training in EU legislation about Food Additives. Procedures and training to official inspectors to simplify the update of the Centro America Custom's list of Food Additives. Guatemala
Name and address of employer	QI/European Commission
Type of business or sector	Food safety
Dates	November 2015
Occupation or position held	Short term expert
Main activities and responsibilities	MMSS Project Support to Modernization of Mongolia's Standardisation System EuropeAid/134305/C/SER/MNActivity R2B2 Training in Veterinary Medicines Regulations and Residue control of Veterinary Medicinal Products in the European Union. Training to official inspectors on Veterinary medicines residues official control requirements and application to import food of animal origin to the EU.
Name and address of employer	EU_Mongolia
Type of business or sector	Food & Veterinary safety
Dates	March 2015
Occupation or position held	Short term Expert
Main activities and responsibilities	(DCI-ALA/2012/023-475) Activity R8. A1 Technical assistance to improve the DIGESA capabilities regarding the procedures for registration and export of food and beverages for human consumption, through the incorporation of risk-based criteria. Drafting manuals on prioritization criteria based on risk for official control and registration of food companies. Training to the Customs Central competent authorities of Peru.
Name and address of employer	Qi/European Commission
Type of business or sector	Food safety
Dates	November 2014 December 2014; June 2016, September 2016; January 2017
Occupation or position held	Expert Tutor
Main activities and responsibilities	"Better Training for Safer Food" Food Improvement Agents (Additives, Flavourings and Enzymes) designed to competent authorities from member States with reference EAHC 2013 249. Lecture on Risk assessment of food improvement agents and Practical session to assess the dietary exposure of food improvements agents by using different methods. To conclude on risk management decisions based on the results of the exposure calculations. Valencia Spain / Trim Ireland
Name and address of employer	BTSF
Type of business or sector	Food safety
Dates	May 2014
Occupation or position held	Training Coordinator
Main activities and responsibilities	Training coordinator in BTSF: EU-China Workshop on Risk Analysis Principles applied to Food Safety Beijing 19-23 May 2014. Lectures on principles, concepts and methods of risk analysis, risk assessment at level, EU risk management EU law on Veterinary Medicinal Products, contaminants and Pesticide residues, design management and evaluation of official control plans for , chemical risks, including environmental contaminants (heavy metals, dioxins, etc.) and residues of pesticides and veterinary drugs in food products.
Name and address of employer	BTSF- Non European Countries
Type of business or sector	Food safety
Dates	April 2014-to September 2015
Occupation or position held	Expert tutor

Main activities and responsibilities	Expert tutor in BTSF program "Residues of Veterinary Medicinal Products in food of animal origin" Twelve 3-days training sessions between 2014 and 2015. The training started in Venice Italy on 22-25 April 2014. Lectures and Study cases on Pesticide residues on food of animal origin and in Veterinary Medicinal Products and Identification rules for Equidae. Italy, Ireland, Spain, Poland
Name and address of employer	BTSF
Type of business or sector	Food and Veterinary safety
Dates	February 2013
Occupation or position held	Expert tutor
Main activities and responsibilities	Better training for safer food. "Food Additives EAHC/2011/BTSF/01" : "Legislation, evaluation and registration of food additives and control of their proper use and marketing" tutor in Practical sessions to understand the use of the new EU food additives database and Specifications of food additives and their authorised use. Valencia Spain
Name and address of employer	BTSF
Type of business or sector	Food safety
Dates	April 2012 to September 2013
Occupation or position held	Expert tutor
Main activities and responsibilities	Expert tutor in BTSF destined to staff of the competent authorities of Member States "Control on residues of veterinary medicinal products in food of animal origin": preparation and implementation of lectures and practical sessions in twelve training sessions during 2012-2013 started in Prague in April 2012.
Name and address of employer	BTSF-
Type of business or sector	Food safety
Dates	May 2012 June 2012
Occupation or position held	International Short term expert
Main activities and responsibilities	Technical assistance as International Short term expert Project PROMESAFI DCI-ALA/2008/019-470 four weeks for the Mission 2322A" Designing training strategy on EU food safety legislation and a drawing up Manual of Procedure for training on the EU food safety requirements for products of animal origin. Training to the Customs' official inspectors on rules for imported food products to the EU. San Jose
Name and address of employer	EU_Costa Rica
Type of business or sector	Food safety
Dates	December 2011
Occupation or position held	Expert Tutor
Main activities and responsibilities	Expert tutor and Technical assistant in three-day seminar "Control Programs on Chemical residues in food animal and non-animal origin. Evaluation of Mercosur Programmes comparing to UE, findings and corrective actions. Lectures discussions and meetings with competent authorities in Argentina about residues control programmes and Laboratorial aspect. Asunción 12 al 14 December 2011 and Buenos Aires 15, 16 December 2011(Convenio ALA/2005/17887). Asunción, Buenos Aires
Name and address of employer	EU_Mercosur
Type of business or sector	Food safety
Dates	September 2010
Occupation or position held	Expert Tutor
Main activities and responsibilities	Expert tutor in EU-ASEAN Cooperation forum on risk assessment on pesticide residues held in Kuala Lumpur 28-30 September 2010 (SANCO7E2/20097SI2.541 417).Lectures and discussions.
Name and address of employer	BTSF
Type of business or sector	Food safety
Dates	September 2010 – December 2010

Occupation or position held	Expert Tutor
Main activities and responsibilities	Expert tutor in 5 day training seminar/workshop on EU "New concepts and rules on food/feed legislation in the EU". 30 hours of lectures and practical sessions-discussions. Training project on animal health plant health, hygiene and official controls on food including official controls at customs (Convenio ALA72005/17887 EU-MERCOSUR) held in Paraguay 20-24 September 2010. Asuncion, Paraguay / Montevideo, Uruguay
Name and address of employer	EU-Mercosur
Type of business or sector	Food safety
Dates	October 2009
Occupation or position held	Expert tutor
Main activities and responsibilities	Expert in BTSF seminar "EU legislation on PPP and residues in fruits and vegetables held in Buenos Aires Argentina 20-22 September 2009. Lectures and practical sessions on customs procedures for non-animal origin products. Buenos Aires, Argentina
Name and address of employer	BTSF
Type of business or sector	Food safety
Dates	Jan 2009
Occupation or position held	Expert Tutor
Main activities and responsibilities	EU – Peru: Cooperation project on Technical Assistance related to Trade – Support to the National Strategic Exporting Program (PENIX 2003 – 2013) (ALA/2004/016-913). Support to the training programme with the implementation of three workshops on the adoption and application of the sanitary and Phytosanitary EU regulations for exports to the EU, undertaken in the cities of Trujillo, Piura and Arequipa. Training to official control authorities and stakeholders on rules for imported food products to the EU.
Name and address of employer	EU-Peru
Type of business or sector	Food safety
Dates	Sep 2007 – Sept. 2008
Occupation or position held	Long term Expert
Main activities and responsibilities	Twinning light PL 2006 IB AG 02 TL. Collaboration in: - Drawing up of the project under "Twinning Light manual 2007": Designing of the training activities. Selecting the subjects to be covered on the courses, seminars and workshops. Coordinating experts. Communicating and coordinating the activities with Polish authorities. Preparation of agendas of inception meetings, steering committees. Collaborating in project reporting: inception report, start-up reports, and quarterly report. Training activities as an expert: Participating in six training courses more than 50 hours of seminars and discussions, 15 lectures about monitoring and control of zoonosis and zoonotic agents. Madrid and Poland
Name and address of employer	Twinning Light Strengthening of the Polish Veterinary Administration
Type of business or sector	Food safety
Dates	September 2004 to November 2004
Occupation or position held	Superior Technician Public Health
Main activities and responsibilities	Management of the official control and monitoring Plan of biological contaminants in food. Madrid
Name and address of employer	Public Health Directorate General
Type of business or sector	Food safety
Dates	November 2003 to September 2004
Occupation or position held	Technical Health Director

Main activities and responsibilities	Hygiene and Food Safety Department. Regional Administration Official veterinary inspection services at slaughterhouses and cutting plants: official control, verification and audit of HACCP systems of business operators. Madrid
Name and address of employer	Public health and Food Directorate General
Type of business or sector	Food safety
Dates	November 1998 to April 2004
Occupation or position held	Executive and general secretary
Main activities and responsibilities	Management and organization of scientific continuing education programs, International Annual conferences and Meetings, management and coordination of scientific programs and administrative tasks. Madrid
Name and address of employer	Spanish Association of Equine Practitioners
Type of business or sector	Animal Health and Welfare
Dates	January 1998 - November 2003
Occupation or position held	Project Manager
Main activities and responsibilities	Sanitary programs, Animal Health and Welfare: Development of Regional Equine Identification and Registration Program for the Animal Health Directorate at the Regional Administration. Madrid
Name and address of employer	Official Veterinary College
Type of business or sector	Animal Health and Welfare
Dates	January 2002 June.2002
Occupation or position held	Professor
Main activities and responsibilities	Associate Professor of Animal Pathology. Department of Animal Pathology II: Lectures Practical sessions on equine pathology. Madrid
Name and address of employer	University Complutense of Madrid. Veterinary School
Type of business or sector	Animal Health and Welfare
Dates	November 1991 April 2004
Occupation or position held	Veterinary Surgeon
Main activities and responsibilities	Private practice specialist in equine sports medicine, Official Veterinarian for the International Equine Federation. Madrid
Name and address of employer	Private Equine Practice
Type of business or sector	Animal Health and Welfare

Education and training

Dates	June 2007
Title of qualification awarded	Certificate
Principal subjects/occupational skills covered	Food Safety Risk Analysis
Name and type of organisation providing education and training	JIFSAN (Joint Institute on Food Safety and Applied Nutrition. University of Maryland. EEUU
Dates	January – June 2005
Title of qualification awarded	Master
Principal subjects/occupational skills covered	Public Health

Name and type of organisation providing education and training	National Public Health Administration
Dates	1998 – 1999
Title of qualification awarded	Investigation sufficiency
Principal subjects/occupational skills covered	PhD Courses on Veterinary Pharmacology and Toxicology
Name and type of organisation providing education and training	Complutense University of Madrid. Veterinary School Pharmacology and Toxicology Department
Dates	1983 –1991
Title of qualification awarded	Degree
Principal subjects/occupational skills covered	Specialist in Veterinary Medicine and Animal Health
Name and type of organisation providing education and training	Complutense University of Madrid, Veterinary School

Personal skills and competences

Mother tongue(s) **Spanish**

Other language(s)

Self-assessment

European level (*)

English

Understanding				Speaking				Writing	
Listening		Reading		Spoken interaction		Spoken production			
C2	Proficient	C2	Proficient	C1	Proficient	C2	Proficient	C1	Proficient

(*) [Common European Framework of Reference for Languages](#)

Social skills and competences

- Adaptation to particularities of multicultural ambiances.
- Experience in relation with other countries, administrations, sectors and media.
- Aptitudes for direction of working groups and to work with multidisciplinary groups

Technical skills and competences

- Knowledge of the European institutions at technical level.
- Management of Official control programs in food and feed, design of procedures, manuals and technical instructions.
- Experience in design, planning and implementation of training in Sanitary and Phytosanitary Standards, Risk analysis to Customs' competent authorities of Non-EU countries.
- High experience in training activities to inspectors on Risk Analysis in food safety EU legislation regarding Food safety standards.
- Publications in magazines and communications at congresses

Computer skills and competences

Advanced computing capacities and competences: Word, Excel, PowerPoint, Outlook, Access, and Adobe Acrobat Pro

Additional information

Contact person for references Ana Rodríguez Castaño arodrigc@mapama.es Executive Director Centro Nacional de Capacitación Agraria (CENCA).

CURRICULUM VITAE

18/05/2015



Title and name

Professor Anthony Richard Hardy

Nationality

UK

Panel / Scientific Committee

Scientific Committee (SC)

Education

- Bachelor of Arts (BA Honours), 1972, University of Oxford, UK
 - Master of Arts (MA), 1973, University of Oxford, UK
 - Doctor of Philosophy (PhD), 1977, University of Aberdeen, UK
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Work Experience

2009– 2010	Centre for Low Carbon Futures, University of York, Heslington Hall, York, YO10 5DG, UK	Interim Director Providing research and advice to low carbon businesses.
1990– 2009	Central Science Laboratory, UK Ministry of Agriculture, Fisheries and Food (MAFF) later became Department for Environment, Food and Rural Affairs (Defra) Central Science Laboratory, Sand Hutton, York, YO41 1LZ, UK	Science Director (Agri-Environment) Research, senior management, scientific services, policy advice.
1976– 1990	Tolworth Laboratory, Surbiton, Surrey: Worplesdon	Research ecotoxicologist and environmental chemist, Team leader, Head of Birds and Mammals Research Department

	<p>Laboratory, Guildford, Surrey Harpenden Laboratory, Harpenden, Hertfordshire: Slough Laboratory Slough, Berkshire</p> <p>All forerunner central MAFF laboratories that were combined to become CSL)</p>	<p>Field researcher on the population dynamics and behavior of rats in farmland. Development of field methodology and advised industry through the pesticides registration department on field trials for pesticides.</p>
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Scientific expertise and risk assessment experience

With a scientific background as a research ecologist, environmental chemist and ecotoxicologist, the main areas of my research and risk assessment experience are in:

- the environmental impact of agricultural chemicals (pesticides) on wildlife
- the development of field trials and methods to assess impact on individuals and populations
- the environmental impact of different farming systems on target and non-target wildlife
- the environmental risk assessment of genetically modified organisms
- wider food safety risk assessment of various chemical and biological agents, pathogens and contaminants
- over 35 years of risk assessment experience on national and international regulatory pesticide and food safety committees
- risk assessment terminology

Most relevant scientific publications within the fields of EFSA

Main areas of publication: ecology, environmental chemistry and ecotoxicology.

Publications:

Karin M. Nienstedt, Theo C.M. Brock, Joke van Wensem, Mark Montforts, Andy Hart, Alf Aagaard, Anne Alix, Jos Boesten, Stephanie K. Bopp, Colin Brown, Ettore Capri, Valery Forbes, Herbert Köpp, Matthias Liess, Robert Luttik, Lorraine Maltby, José P. Sousa, Franz Streissl, Anthony R. Hardy (2012). Development of a framework based on an ecosystem services approach for deriving specific protection goals for environmental risk assessment of pesticides. *Science of the Total Environment* 415: 31–38

Boxall AB, Hardy A, Beulke S, Boucard T, Burgin L, et al. (2008 Impacts of Climate Change on Indirect Human Exposure to Pathogens and Chemicals from Agriculture. *Environ Health Perspect* 117(4): doi:10.1289/ehp.0800084

<http://www.ehponline.org/docs/2008/0800084/abstract.html>

Roberts T M and A R Hardy (2005). Risk assessment of genetically modified plants, food and feed in the European Community. Conference Proceedings of International Conference on Biosafety, 21-23 February 2005, Oman Vol. 2 (17 pp).

Greig-Smith P W, Thompson H M, Hardy A R, Bew M H, Findlay E and Stevenson J H (1994) A review of poisoning of honeybees (*Apis mellifera*) by agricultural pesticides in Great Britain 1981-91. *Crop Protection* 13: 567 - 581.

Hardy A R, Westlake G E, Lloyd G A, Brown P M, Greig-Smith P W, Fletcher M R, Tarrant K A, Stanley P I (1993). An intensive field trial to assess hazards to birds and mammals from the use of methiocarb as a bird repellent on ripening cherries. *Ecotoxicology*. 2: 1-31.

Greig-Smith P W, Frampton G K and Hardy A R (1992). Eds. *Pesticides, Cereal Farming and the Environment. (The Boxworth Project)*. HMSO 288p.

Hardy A R, Stanley P I and Greig-Smith P W (1987). Birds as indicators of the intensity of use of agricultural pesticides in the UK. In: *The Value of Birds*. Diamond A W and Fillion, F L (Eds). International Council for Bird Preservation, Technical Publication 6, Cambridge, England, pp 119-132.

Hardy A R, Fletcher M R and Stanley P I (1986). Twenty years of vertebrate wildlife incident investigations by MAFF. *State Veterinary Journal* 117: 182-192.

Stanley P I and Hardy A R (1984). The environmental implications of current pesticide usage on cereals. In: *Agriculture and the Environment*. Jenkins, D E (Ed). pp 66-72. ITE Symposium No. 13, Institute of Terrestrial Ecology, Cambridge.

Hardy A R and Stanley P I (1984). The impact of the commercial agricultural use of organophosphorus and carbamate pesticides on British wildlife. In: *Agriculture and the Environment*. Jenkins, D E (Ed). pp 72-80. ITE Symposium No. 13, Institute of Terrestrial Ecology, Cambridge.

Europass Curriculum Vitae



Alberto Mantovani

Personal information

First name(s) / Surname(s) **Mantovani Alberto**
 Address(es) Via Giorgio Baglivi, 8 – 00161 Roma, Italia
 Telephone(s) +39 06 4990 2815

E-mail **alberto.mantovani@iss.it**

Nationality Italian
 Date of birth 1956, February 22
 Gender Male

Work experience

Dates 2007-today
 Occupation or position held Research Director
 Main activities and responsibilities *Scientific activity at the Italian National Health Institute (Istituto Superiore di Sanità, ISS)*
 Director of the Food and Veterinary Toxicology Unit, with main focus on *endocrine disrupters* and *trace elements*, including *nanomaterials*.
 In the current re-organization of the ISS, the Unit has been included (kune 2017) in a larger section on Food Nutrition and Health
 a) *Cordination of national and international projects*
 - Coordinator:
 “Endocrine Disruptors in silico/in vitro Evaluation and Substitution for Industrial Application - LIFE EDESIA”- Project funded within the EU programme LIFE LIFE, duration 2012-2016, website (with English version) <http://www.iss.it/life>;
 - “An integrated sensors and biosensors system (BEST) aimed at monitoring the quality, health and traceability of the chain of the bovine milk – ALERT”. Project funded by the Italian Ministry for Economic Development, duration 2011-17, website (with English version) <http://www.alert2015.it>;
 - “Study in model areas on the environmental and health impact of some emerging chemical contaminants (endocrine disrupters): living environment, reproductive outcomes and repercussions in childhood – PREVIENI” . Project funded by the Italian Ministry for Environment and Protection of Territory and Sea , duration 2008-11, website (with English version) <http://www.iss.it/prvn/>;
 - “Bladder Extrophy-Epispadias Complex and Exogenous Risk Factors - BLADE” a small-scale project spinned from the instituional activities on endocrine disrupting chemicals which I co-ordinate at the Istituto Superiore di Sanità (ISS) since 2003 (see the dedicated ISS web area with full English version: <http://www.iss.it/inte>). BLADE was funded by the ISS-U.S. NIH collaborative programme, duration 2008-2010,
 In addition, in the last 10 years I had/am principal investigator of ISS Unit:in the following large-scale EU projects
 - “An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century – EUToxRisk”, a Horizon 2020 project, website, <http://www.eu-toxrisk.eu>,
 - “Chemicals as contaminants in the food chain: a Network of Excellence for research, risk assessment and education – CASCADE” within the 6th Framework Programme, where I co-organized the CASCADE Spring School “Food Safety and Environment: Health Risk Assessment. A focus on the endocrine active compounds “ (2005)
 – Integrated Project (6th Framework Programme) “Development of a novel approach in hazard and risk assessment of reproductive toxicity by a combination and application of in vitro, tissue and

sensor technologies - ReProTect" duration 2004-2010, website <http://www.reprotect.eu>, where I was co-ordinator of the research area IV "Cross-cutting technologies"

Risk assessment and advisory activities

European Food Safety Authority (EFSA)

I was member of *EFSA FEEDAP Panel (feed additives and substances used in animal feeds)*, <http://www.efsa.europa.eu/en/panels/feedap.htm> on 2003-12; on 2007-12 I chaired the FEEDAP working group on Trace Elements and on 2009-(June) 2012 I have been FEEDAP vice-chair. On 2012-15 I supported FEEDAP activities as external expert in the working groups on Trace Elements and Vitamins in feeds. Since July 2015 I am again member of FEEDAP; since October 2015 I am the chair the Trace Elements Working Group.

From July 2012 to June 2015 I have been member of *EFSA Panel on plant protection products and their residues (PPR)*, <http://www.efsa.europa.eu/en/panels/pesticides.htm>. In this period I contributed as member of the drafting working to some major opinions such as those on Identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile (2013)

-Relevance of dissimilar mode of action and its appropriate application for cumulative risk assessment of pesticides residues (2013)

-Developmental neurotoxicity potential of acetamiprid and imidacloprid (2013).

- Good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products (2014)

I continued to collaborate with PPR till 2016 as external expert (see below, EFSA opinions)

On 2012-15 I participated as member of the *EFSA Working Group on Emerging Risks*, where I represented the PPR Panel (<https://ess.efsa.europa.eu/doi/doiweb/wg/677630>)

From 2003 I have collaborated with other EFSA activities, namely:

Risk assessment of organotin (2004, Panel on Contaminants -CONTAM);

Replacement, reduction and refinement of animal testing, (2009, Scientific Committee),

Data Sources on Emerging Risks (2011, Emerging Risk Unit)

Bisphenol A (2011, Panel on Food Contact Materials-CEF)

Thresholds of Toxicological Concern (2012, Scientific Committee).

ProMeTheus project on the management of uncertainties (2016-ongoing)

ECHA/EFSA Endocrine Disruption Guidance Consultation Group

Other activities

- Member (2011-13 and 2015-18) of the National Food Safety Committee, an independent risk assessment body providing scientific opinions upon request by the Italian Health Ministry. I was member of the drafting working groups for the followings: erucic acid in foods and feeds (2015); health risks from the use of antibiotics in honey bee farming (2016); exposure to aluminium through food contact materials (2017).

- upon request by the Italian Competent Authority, I provide scientific advice on the classification of suspected reproductive toxicants and endocrine disruptors within the REACH, e.g., on: Chloromethane (2014); Boric acid and borates (2014); Methanol (2014); Octabenzene (2015)

- I am one of Italian experts participating to the OECD activity on Endocrine Disruptors Testing and Assessment: I am currently in the Steering Group providing advice on GD 150, the new document on assessment criteria, assays and endpoints.

- Invited expert to:

Scoping Workshop of the EU Collab4Safe project (Bruxelles, May 2013)

Joint FAO/WHO expert meeting on hazards associated with animal feed. (May 2015, FAO).

Internazional workshop "Food Safety on a global scale: what are the emerging risks?" organized by the Catholic University within Expo2015 (Milano, September 2015)

International Expert Meeting on Endocrine Disruptors (April 2016, Berlin) organized by BfR and EC (<http://www.efsa.europa.eu/en/events/event/160411a>)

Workshop "Mapping commonalities and differences in approaches for testing and assessment of endocrine disruptors within the EU and among relevant international trading partners" organized by Brunel University (London-UK) and EC – DG ENV (Bruxelles, October 2016)

32)

Workshop on Thyroid Disruption organized by Brunel University (London-UK), ANSES (FR) and EC DG ENV (Paris, March 2017)

- member (since 2008) and vice-chair (since 2015) of the International Evaluation Committee organized by the French National Research Agency (ANR) to assess project proposals presented at the calls on "Food and Food industries Research"

- Invited speaker in two meetings organized by the EU Parliament:

"Endocrine disruptors and impact on health" (September 2012, my talk "Endocrine disruptors: the standpoint of a Public Health Institute")

"Health risk prevention in EU areas characterized by High Environmental Pressure" (December 2016,

my talk "From AOPs to biomarkers: the contribution of toxicological data sets to health risk prevention in children")

I am currently (September 2016-September 2017) president of the European Teratology Society (ETS, www.etsoc.com): chair of the ETS Conference to be held in Budapest on 4-7 September 2017 and Guest Editor of the special issue of Reproductive Toxicology dedicated to the ETS Conference <http://www.sciencedirect.com/science/journal/08906238/72?sd=1>

Name and address of employer	Istituto Superiore di Sanità (Italian National health institute) Viale Regina Elena, 299 00161 Roma,
Type of business or sector	Research
Dates	1992-2006
Position held	Senior scientist
Main activities and responsibilities	I have worked till 2003 in the laboratory of Comparative Toxicology and Ecotoxicology and afterwards at the newly established Department of Food and Animal Health, since 2006 Dept of Veterinary Public Health and Food Safety. During this period I co-ordinated a unit on reproductive and developmental toxicology with special focus on endocrine disrupters: since 2000 I co-ordinated the first national project on endocrine disrupters, whose activities have been disseminated through the website http://www.iss.it/inte . I participated to a number of international risk assessment activities: Safety of Residues Working Party (veterinary drug residues at EMA (1994-9), OECD working on endocrine disrupters testing and assessment (2000-9); EFSA FEEDAP Panel (2003-onward see above); I co-chaired the Technical Working Group "Endocrine Disrupters" within SCALE project (2002-2003) - EU Environment and Health strategy
Name and address of employer	Istituto Superiore di Sanità (Italian National health institute) Viale Regina Elena, 299 00161 Roma,
Type of business or sector	Research
Dates	1985-1991
Position held	Junior staff scientist
Main activities and responsibilities	Organizing a unit on in vivo reproductive and developmental toxicology- External expert of the National toxicological Commission, and of the National Commission on pesticides
Name and address of employer	Istituto Superiore di Sanità (Italian National health institute) Viale Regina Elena, 299 00161 Roma,
Type of business or sector	Research
Education and training	
Dates	1982
Title of qualification awarded	Master of Science in Veterinary Public Health
Principal subjects	Veterinary public health
Name and type of organisation providing education and training	University of Edinburgh
Dates	1979
Title of qualification awarded	Doctor in Veterinary Medicine

Principal subjects
Name and type of organisation providing education and training

Veterinary medicine
University of Bologna (Italy)

Mother tongue(s)

Italian

Other language(s)
Self-assessment
European level (*)

English
French

Understanding		Speaking		Writing	
Listening	Reading	Spoken interaction	Spoken production		
excellent	excellent	excellent	excellent	excellent	
good	excellent	good	good	fair	

(*) [Common European Framework of Reference for Languages](#)

LIST OF INTERNATIONAL PAPERS 2007-2017

Peer-reviewed papers (by scientific topic)

Endocrine Disruptors

- Baldi F, Mantovani A. (2008) A new database for food safety: EDID (Endocrine disrupting chemicals - Diet Interaction Database). *Ann Ist Super Sanita*. 44: 57-63.
- Giordano F, Carbone P, Nori F, Mantovani A, Taruscio D, Figà-Talamanca I. (2008) Maternal diet and the risk of hypospadias and cryptorchidism in the offspring. *Paediatric and Perinatal Epidemiology*. 22: 249-260.
- Maranghi F, Tassinari R, Moracci G, Macri C, Mantovani A. (2008) Effects of a low oral dose of diethylstilbestrol (DES) on reproductive tract development in F1 female CD-1 mice. *Reprod Toxicol*. 26:146-50.
- Santini F, Mantovani A, Cristaudo A, Rago T, Marsili A, Buselli R, Mignani A, Ceccarini G, Bastillo R, Taddei D, Ricco I, Vitti P, Pinchera A. (2008) Thyroid function and exposure to styrene. *Thyroid*. 18: 1065-9.
- Mantovani A, Frazzoli C, La Rocca C. (2009) Risk assessment of endocrine-active compounds in feeds. *Vet J*. 182, 392-401.
- Latini G, Knipp G, Mantovani A, Marcovecchio ML, Chiarelli F, Söder O. (2010) Endocrine disruptors and human health. *Mini Rev Med Chem*. 10: 846-55.
- Maranghi F, Lorenzetti S, Tassinari R, Moracci G, Tassinari V, Marcocchia D, Di Virgilio A, Eusepi A, Romeo A, Magrelli A, Salvatore M, Tosto F, Viganotti M, Antoccia A, Di Masi A, Azzalin G, Tanzarella C, Macino G, Taruscio D, Mantovani A (2010). In utero exposure to di-(2-ethylhexyl) phthalate affects liver morphology and metabolism in post-natal CD-1 mice. *Reprod Toxicol*. 29: 427-32.
- Tait S, La Rocca C, Mantovani A (2011). Exposure of human fetal penile cells to different PCB mixtures: transcriptome analysis points to diverse modes of interference on external genitalia programming. *Reprod Toxicol*. 32: 1-14.
- La Rocca C, Alessi E, Bergamasco B, Caserta D, Ciardo F, Fanello E, Focardi S, Guerranti C, Stecca L, Moscarini M, Perra G, Tait S, Zaghi C, Mantovani A (2012). Exposure and effective dose biomarkers for perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in infertile subjects: Preliminary results of the PREVIENI project. *Int J Hyg Environ Health*. 215: 206-11.
- Maranghi F, Mantovani A (2012). Targeted toxicological testing to investigate the role of endocrine disruptors in puberty disorders. *Reproductive Toxicology* 33: 290-6.
- Maranghi F, Tassinari R, Moracci G, Altieri I, Rasinger JD, Carroll TS, Hogstrand C, Lundebye AK, Mantovani A (2013). Dietary exposure of juvenile female mice to polyhalogenated seafood contaminants (HBCD, BDE-47, PCB-153, TCDD): comparative assessment of effects in potential target tissues. *Food Chem Toxicol*. 56: 443-9.
- Maranghi F, Tassinari R, Mantovani A (2013). Toxicological assessment of drugs that effect the endocrine system in puberty-related disorders. *Expert Opinion on Drug Metabolism and Toxicology* 9: 1309-16.
- Pouokam GB, Ajaezi GC, Mantovani A, Orisakwe OE, Frazzoli C (2014). Use of Bisphenol A-containing baby bottles in Cameroon and Nigeria and possible risk management and mitigation measures: community as milestone for prevention. *Science of the Total Environment* 15: 296-302
- Smeriglio A, Trombetta D, Marcocchia D, Mantovani A, Lorenzetti S (2014). Intracellular distribution and biological effects of plant bioactives in a sex steroid-sensitive model of human prostate adenocarcinoma. *Anticancer Agents in Medicinal Chemistry* 14: 1386-96
- La Rocca C, Tait S, Guerranti C, Busani L, Ciardo F, Bergamasco B, Stecca L, Perra G, Mancini FR, Marci R, Bordi G, Caserta D, Focardi S, Moscarini M, Mantovani A (2014). Exposure to endocrine disruptors and nuclear receptors gene expression in infertile and fertile women from different Italian areas. *International Journal of Environmental Research and Public Health* 11: 10146-164.
- Tait S, Tassinari R, Maranghi F, Mantovani A (2015). Toxicogenomics analysis of placenta samples from mice exposed to different doses of BPA. *Genomics Data* 4: 109-11
- Fucic A., Ivankovic S, Ivankovic D, Stojkovic R, Attias L, Mantovani A (2015). Testosterone-induced micronuclei and increased nuclear division rate in L929 cell line expressing the androgen receptor. *Toxicology in Vitro* 29: 1021-5
- Tait S, Tassinari R, Maranghi F, Mantovani A (2015). Bisphenol A affects placental layers morphology and angiogenesis during early pregnancy phase in mice. *Journal of Applied Toxicology* 34: 1278-91
- La Rocca C, Tait S, Guerranti C, Busani L, Ciardo F, Bergamasco B, Perra G, Mancini FR, Marci R, Bordi G, Caserta D, Focardi S, Moscarini M, Mantovani A (2015). Exposure to endocrine disruptors and nuclear receptors gene expression in infertile and fertile men from Italian areas with different environmental features. *International Journal of Environmental Research and Public Health* 12: 12425-45.

Heindel JJ, vom Saal FS, Blumberg B, Bovolin P, Calamandrei G, Ceresini G, Cohn BA, Fabbri E, Gioiosa L, Kassotis C, Legler J, La Merrill M, Rizzir L, Machtinger R, Mantovani A, Mendez MA, Montanini L, Molteni L, Nagel SC, Parmigiani S, Panzica G, Paterlini S, Pomatto V, Ruzzin J, Sartor G, Schug TT, Street ME, Suvorov A, Volpi R, Zoeller RT, Palanza P. Parma Consensus Statement on Metabolic Disruptors. *Environmental Health* (2015) Jun 20;14:54. doi: 10.1186/s12940-015-0042-7.

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EFSA Opinions and documents (2014-17)

in EFSA all Panel members are responsible for adopted opinions and should contribute to their finalization: for shortness's sake I mention the opinions to which I directly contributed as chair or member of the drafting working group in the last three years of my EFSA membership

PPR (Plant Protection Products and their Residues)

Good modelling practice in the context of mechanistic effect models (2014)

Guidance on the establishment of the residue definition for dietary risk assessment (2016)

Investigation into experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia (2017)

FEEDAP (substances used in animal feeds)

Vitamin D3 (cholecalciferol) for all species (2014); vitamin D3 addition to feedingstuffs for fish (2017)

Vitamin B2 produced by *Bacillus subtilis* (2014)

Vitamin B12 (2015)

Inositol for fish, dogs and cats (2014)

Vitamin K3 (2014)

Riboflavin (2014)

Iron compounds (2016); ferrous sulphate monohydrate (2014); ferrous sulphate heptahydrate (2014); ferrous carbonate (2015); ferric oxide (2016); iron dextran for suckling piglets (2017)

Selenium-enriched yeasts (2014), (2016) and (2017); DL-Selenomethionine (2014); Sodium selenite (2015);

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Manganese compounds (2015); Manganese hydroxylchloride (2016)
Zinc compounds (2015); Zinc chelate of L-lysinate-HCl (2015); Zinc chelate of methionine sulphate (2017)
Copper compounds (2015); Copper chelate of L-lysinate-HCl (2014); Dicopper oxide (2016)
Solanum glaucophyllum standardised leaves as feed material (2015)
Phaseolus vulgaris lectins as a zootechnical additive for suckling piglets (2015)
Fumonisin esterase as a technological additive for avian species (2016)
Conjugated linoleic acid methylester for pigs and cows (2016)
Lanthanide citrate as a zootechnical additive for weaned piglets (2016)
L-Tryptophan produced by fermentation with Escherichia coli (2017)

In the same period I also contributed to the *Working Group on Emerging Risks* with the production of two Technical Reports
A systematic procedure for the identification of emerging chemical risks in the food and feed chain (2015)
Identification of emerging risks: an appraisal of the procedure trialled by EFSA and the way forward" (2015)).

***Signed confidentiality agreements of
IVC 2018 members***

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): KOETER. HERMANUS. B.W.M.

Date and place of birth: 01/10/1947 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 client 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, 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 the client to require compliance with this declaration, nor does it affect the right of the client 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, 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)

LUCCA ITALY 14/2/2018
(town/city in which signed, date of signature)

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): AUTIO, SARI PATVIKKI

Date and place of birth: 31.8.1961 RAAHE, FINLAND

Working for: NATURAL RESOURCES INSTITUTE FINLAND (LUKE)
FINNISH ORGANIC RESEARCH INSTITUTE

In the position of: RESEARCH MANAGER

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 client 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, 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)

HELSINKI FINLAND, 19.2.2018
.....
(town/city in which signed, date of signature)

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names):..... **Carretero Gómez María Mar**.....

Date and place of birth: **Madrid, Spain 9th October 1965**

Working for:..... **Community of Madrid, Public Health Directorate. Food Safety Area**.....

In the position of:..... **Inspector**.....

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 client 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, 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)

Madrid, 18th April 2018

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

Declaration of confidentiality provided by third parties

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

HARDY, ANTHONY RICHARD

Date and place of birth: 6th May 1951, BIRMINGHAM, UK

Working for: RETIRED, working like EFSA as external expert.

In the position of: Chair of Scientific Committee

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 client 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, 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 the client to require compliance with this declaration, nor does it affect the right of the client 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, 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)

GRAYSHTOFT, UK. 19/02/2018
(town/city in which signed, date of signature)

Declaration of confidentiality provided by third parties

The undersigned

(surname, followed by first names):

MANTOVANI
ALBERTO

Date and place of birth:

BOLOGNA 22/02/1956

Working for:

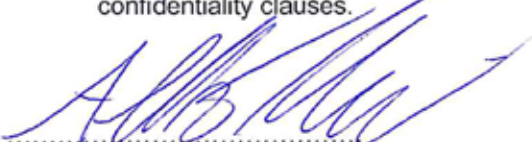
ISTITUTO SUPERIORE DI SANITA'

In the position of:

RESEARCH 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 client 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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(Signature)

ROMA 20/02/2018

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

Signed Declaration of interests IVC members

***Signed Declaration of interests
IVC members***

ORANGE HOUSE

PARTNERSHIP vzw

Declaration

1. Considering the above, have you, or any of your first degree family members, any interest in: (i) The mission and activities of OHP in general, (ii) the activity or project at hand, (iii) the project team you have been invited to join?

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

2. Could any of the above declared interests be considered as constituting a real, potential or apparent conflict of interest?

yes no If yes, please provide details below

3. 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.

H. KOËTER
Name

H. Koeter
Signature

7-12-2017
Date

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?

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.

Sari Autio

Name

Sari Autio

Signature

7.12.2012

Date

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yes	no
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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
Chair	The Scientific Committee of the European Food Safety Authority	I have	Current

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.

Anthony Richard Hardy



6 December 2017

Name

Signature

Date

DECLARATION OF INTEREST FORM

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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

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Alberto Mantovani		9/12/2017
Name	Signature	Date

DECLARATION OF INTEREST FORM

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Declaration

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yes	no
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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

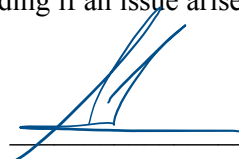
Is there anything else that could affect your objectivity or independence in the activity or the group at hand?

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.

María Mar Carretero Gómez

Name



Signature

April 18th 2018

Date

2nd International Visitation Committee, 2018 (2nd IVC)

Final Action Plan

Establishment of the 2nd International Visitation Committee (2nd IVC)

1. At the request of the Chair of the Ctgb Board, in November 2017, a second international visitation committee was established by Dr. Herman Koëter which was endorsed by the Board on 22nd November 2017. The membership of the 2nd IVC is as follows:

- a. Dr Alberto Mantovani, Istituto Superiore di Sanità (ISS), Italy
- b. Dr Sari Autio, Finnish Organic Research Institute, Finland;
- c. Professor Anthony Hardy, Retired, Independent expert with the European Food Safety Authority;
- d. Dr Herman Koëter, Orange House Partnership, Belgium (Chair)
- e. Dr Mark Lynch, Lynch Consulting, Ireland (until 27 March 2018)
- f. Dr Mar Carretero; Inspector, Food Safety Unit, Public Health Directorate. Community of Madrid; Consultant EU Programme BTSF

The inaugural (preliminary) meeting of 2nd IVC was held at the Brussels office of the Orange House Partnership (OHP) on 17th January 2018.

2. Details of the assignment of the 2nd IVC are provided in the Terms of Reference, agreed between the Ctgb Board and the Chair of the 2nd IVC on 22nd November 2017. The task assigned to the 2nd IVC is to consider and assess:

- a. the scientific quality of the evaluations conducted and Decisions made in the authorization by the Ctgb of plant protection products and biocides;
- b. the degree of 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;
- c. the efficiency and transparency of the organisational arrangements and procedures of the Ctgb having regard to the expectations of all stakeholders (European Commission, Regulatory Authorities of other Member States, industry and the general public);
- d. the effectiveness of Ctgb arrangements to foster the authorisation of 'green' or 'low-risk' products and to stimulate transition to integrated pest management and sustainable farming systems;
- e. impact on the quality of subsequent evaluations and Decisions of perceived and actual conflicts between the requirements of the European Commission and deadlines specified, on the one hand, and on the other, the interpretation of the guidance provided by the competent authorities of the Member States.

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 the light of state-of-the-art science and legal requirements and, (ii) suggestions and advice, as appropriate, on possible improvements to ensure independent, high quality and timely outputs of the Ctgb, in order to promote sustainable pest management systems while optimising the protection of human health and the environment.

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 through the application of a series of quality indicators as described below.

Evaluation of the Scientific Output

4. Evaluation of the quality of the scientific output will be based on: (i) the quality of the scientific staff involved, (ii) the opportunities for scientific staff to keep up-to-date 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 areas of pesticide and/or biocide risk assessment;
- b. The working environment (*e.g.* work pressure, peer review systems and arrangements to facilitate scientific staff keeping up-to-date with new and emerging scientific and evaluative developments);
- c. In depth evaluation of the scientific output by:
 - i. Scrutinizing a random as well as specific selection of Draft Assessment Reports (DARs) and Competent Authority Reports (CARs) for active substances prepared by the Ctgb, applying a series of quality indicators as described below;
 - ii. Scrutinizing a random as well as specific selection of scientific evaluations prepared by the Ctgb for national and zonal approval of plant protection and biocidal products, applying a series of quality indicators as described below;
 - iii. Scrutinizing a random as well as specific selection of scientific evaluations prepared by the Ctgb, based upon evaluations prepared by other Member States, applying a series of quality indicators as described below;
 - iv. Scrutinizing other types of scientific output such as lectures at scientific symposia, congresses, *etc.*, scientific publications, guidance documents, rebuttals (counter-arguments), *etc.*, against the quality indicators developed.

5. Evaluation of the selected outputs will be done by the individual members of the 2nd IVC, applying a common grading system, followed by the sharing and comparison of their evaluations and the development of a common 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 management and the rationale for Decisions made. In its evaluation of the quality of the Board's decision-making process, the Committee will apply the quality indicators developed.

Development of Indicators

7. A series of semi-quantitative quality indicators have been developed by the 2nd IVC for the evaluation of: (i) the scientific process, (ii) the scientific outcome, (iii) the decision-making processes of the Ctgb, (iv) the transparency and efficiency of the Ctgb, and (v) the fostering of 'green' or 'low-risk' products and of integrated pest management and sustainable farming systems. The indicators agreed upon are as follows:

7.1 Indicators of the quality of the scientific process

- a. The quality (expertise, experience, work history) of scientific staff at the time of recruitment and Ctgb policies to ensure scientific quality would not fall behind developments in science.
- b. Frequency of involvement/consultation of external scientific experts (as a routine or occasional procedure) and their level of expertise, experience and work history.
- c. Staff turnover (high/low), number of vacant posts and average number of applicants to vacant posts for scientific staff.
- d. Evidence of continuous education and training of scientific staff (*e.g.*, congresses, lectures, training courses).
- e. Degree of pressure on the scientific staff resulting from workload and related legal deadlines.
- f. Level of compliance with the adopted risk assessment methodologies.
- g. Extent of adoption of newly developed scientific guidance documentation produced by EFSA and other relevant international organisations, in the period prior to their formal adoption.
- 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 of Decisions.
- j. Level of detail of the peer reviews, and of 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 the independence of Board members and of the expertise of individual Board members in risk analysis and in the management of identified risks.
- m. Level of legal compliance with national and EU legislation.

7.2 Indicators of the quality of the scientific output

- a. Evidence of the knowledge and quality of the scientific staff (*e.g.*, by records of continuous education: post-graduate and refresher courses, attendance at scientific conferences, lectures, publications, invitations, *etc.*).
- b. Evidence of scientific contributions by scientific staff to international risk assessment bodies, such as the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), Codex

Alimentarius Committees, the OECD Working Group on Pesticides, the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), *etc.*

- c. Quality of 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 in terms of data available, data utilized, methodology applied in the assessment, weight of evidence considerations, variability, uncertainties and assumptions, conclusions and recommendations.
- e. Quality of collegial feedback and of peer reviews and their impact on subsequent evaluation procedures, approaches and interpretations.
- f. Degree of consistency and coherence of scientific evaluations.
- g. Degree of acceptance of Ctgb Evaluations and Proposed Decisions, by EFSA for plant protection active substances, and for biocidal active substances by ECHA and by the competent authorities of other Member States for both.
- h. Degree of acceptance by EU Member States in the same zone of Ctgb Evaluations and Proposed Decisions prepared as zonal rapporteur for pesticide preparations.
- i. Outcome of the reviews by the 2nd IVC of Evaluations and proposed Decisions on plant protection and biocidal active substances selected randomly as well as following examination of the minutes of the Ctgb Board and the amount of time taken to deliver Decisions.
- j. Outcome of the reviews by the 2nd IVC of adopted Evaluations and Decisions on plant protection and biocide preparations, selected randomly, as well as following examination of the minutes of the Ctgb Board and the amount of time taken to deliver Decisions.

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

- a. The extent to which the profiles of individual members of the Board and of the Board as a whole fit with its risk analysis and 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 at Board meetings.
- d. The frequency of Board meetings and workload of the Board.
- e. The proportion 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 in 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 and the number amended following consideration by the Board and the reasoning involved, together with an indication of the proportion of Draft Decisions that are not accepted and of the proportion that are amended by the Board.

7.4 Indicators of transparency and efficiency

- a. Degree of transparency of the scientific process, including that of procedures for work-sharing, outsourcing of evaluations, and mutual recognition of assessment reports.

- b. Degree of transparency of the process of risk analysis and risk management by the Board.
- c. Number of Freedom of Information (FOI) requests submitted in relation to the scientific evaluation of risks and/or the risk management process by the Ctgb and the number of requests refused.
- d. Extent to which Ctgb complied with the deadlines specified in relevant EU and National legislation and therefore with the timelines that industry expects.

7.5 Indicators of success in fostering sustainable pest management

- a. Degree of success of the Dutch national action plan on the sustainable use of pesticides (2013-2018).
- b. Progress in the review and updating of the National Action Plan on the sustainable use of plant protection products and details of any changes adopted or proposed.
- c. Number of plant protection products containing low-risk active substances authorised per annum sine 2013 and the extent to which the use of such products has replaced the use of products presenting greater risk.
- d. Degree of success of fiscal incentives introduced to promote the development and implementation of integrated pest management techniques.

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

8. To facilitate the work of the 2nd IVC, a substantial body of documentation and information is required from the Ctgb management, the Ctgb Board and, as appropriate, from external sources. Documentation provided to the 2nd IVC will be treated in strict confidence by its members. In addition, interviews with identified Ctgb Board members and staff and, possibly, with external individuals will be required for a full insight and understanding of the scientific processes, assessment methods and decision-making methods deployed. Dutch organisations other than the Ctgb will be contacted to seek relevant information for which they rather than the Ctgb are responsible.

Requests for Information and Documents Relevant to the Visitation

9. At the introductory meeting with the Board, IVC members will be presented with paper copies and electronic copies of presentations to be given by Ctgb management as appropriate.

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 – those introduced since 2013 to be identified.
- b. Inventory of and access to legal documents relevant for the work of the Ctgb – those introduced or amended since 2013 to be identified.
- c. Access to documentation on evaluation criteria used by scientific staff and management, including staff training policies (initial and continuous training), training records and/or files – those introduced or changed since 2013 to be identified.
- d. Detailed organisational chart of scientific staff and management – changes since 2013 to be highlighted.

- e. CVs, descriptions of functions and responsibilities, including identification of critical functions of all staff and Board Members.
- f. Access to Declarations of Interest (DOI) of all scientific staff over the last 4 years.
- g. Access to reports/documentation on internal and external scientific peer review processes and evaluations.
- h. 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 (4 years) of formal appeals.
- i. Access to written communications with applicants.
- j. Access to documentation on Mutual Agreement (MR) procedures.
- k. A list of plant protection DARs, Biocide CARs and product authorizations granted since January 2014, together with details of the identity (ISO Common names) and content of the active substances they contain and in the case of product authorisations:-
 - the formulation types (GIFAP Code);
 - an indication to identify those for which the Ctgb conducted a zonal evaluation
 - an indication to identify those for which another Member State conducted the zonal evaluation relied upon,
 - an indication to identify those authorised following the mutual recognition of an authorisation granted by another Member State.

In all cases the following additional information is requested – date application received, date of acceptance following administrative and technical completeness check, date scientific evaluation completed and proposed Decision submitted to the Board, and dates of consideration and Decision by the Board

- l. Access to minutes of selected meetings of the Ctgb Board and of meetings of the scientific staff (both scientific and procedural). The meetings selected will be those during which compounds and products selected for review by the 2nd IVC were considered.
- m. Access to operations manuals and SOPs prepared for use by scientific staff and dossier managers (co-ordinators) – those introduced since 2013 to be identified (to the extent not included in item a).
- n. Access to policy and operational guidance prepared for Board members in making management Decisions on proposals submitted – those introduced since 2013 to be identified.

11. The list of requested items as defined in paragraph 10 has been submitted to the Ctgb secretariat on 5th February with the request to provide access to the requested information as soon as possible. Further documentation and information may be requested where necessary by the 2nd IVC during the course of its work.

Caveat with respect to requested documentation

12. It should be clear that, whereas the 2nd IVC considers the above-mentioned requests relevant for carrying out its evaluation, it is aware that many of the available documents addressing some, or all, the requests listed above may not be available in English and that time and budget do not allow for the translation of a substantial number of documents into English. Consequently, the 2nd 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 IVC in the present context. Any suggestions in this respect would be highly appreciated.

Interviews

13. 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 30th and 31st 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.

14. The Committee also wishes to speak with the Board members. Provisionally 25th April is earmarked for these interviews (see also under Time Schedule).

Time Schedule

15. The following time schedule was agreed between the Ctgb Board, the Ctgb management and the 2nd IVC:

- a. November 2017: Agreement on Terms of Reference (ToR) and of the members of the committee.
- b. 17th January 2018: **Preliminary meeting** of the international visitation committee to discuss the Action Plan, strategy, tasks and timing.
- c. First week in February: Draft Action Plan to be provided to the Ctgb and made available for the information of the Board and senior management (*i.e.* methodology and approach of the evaluation, development of indicators, requests for information and documentation). Ctgb to commence compiling documentation requested by the Committee.
- d. 28th February 2018: **Approval** of the Action Plan by the Board. **Second meeting** of the 2nd IVC to meet the Ctgb Board and senior management, to review documentation provided by the Ctgb, to review the list of documentation requested but not yet delivered, to review the list of further documentation to be requested, and to commence compilation of the series of specific questions to be submitted to the Ctgb
- e. Mid-March 2018: The final list of questions from the 2nd IVC to be forwarded to the Ctgb management
- f. March 2018: based on the Action Plan and additional document access requests, Ctgb management and Board will start preparing for the visitation, ensure that access to all documentation requested has been provided expeditiously and arrange for English translations as appropriate.
- g. Late March 2018: **Virtual meeting** of the 2nd IVC to discuss progress; to review responses to requests for documentation received from the Ctgb; to review initial responses to questions posed; first impressions, assessment approaches and practicalities
- h. Second week of April 2018: Supplementary list of requested documentation to be submitted to the Ctgb involving access to documentation on active substance and formulated product scientific evaluations and proposed Decisions as well as that generated by the Board in decision-making.

- i. 2nd April 2018: As appropriate, a **face-to-face or virtual meeting** of the 2nd IVC, including a session with the Board and, as needed, with the senior Ctgb management and / or external individuals. The selection of external experts will be done with the consent of the Ctgb Director and Chairman of the Board, as appropriate.

The meetings on the 25th 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 is required by the Committee, as well as 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.

- j. 23-24 May 2018: a 2-day **visitation** at the Ctgb.
- k. August 2018: **submission** (possibly by electronic mail) to the Ctgb Board and senior management of the draft final report of the visitation mission which is likely to be a concise report with annexes.
- l. 26th September 2018: **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).

Revised 20th February 2018

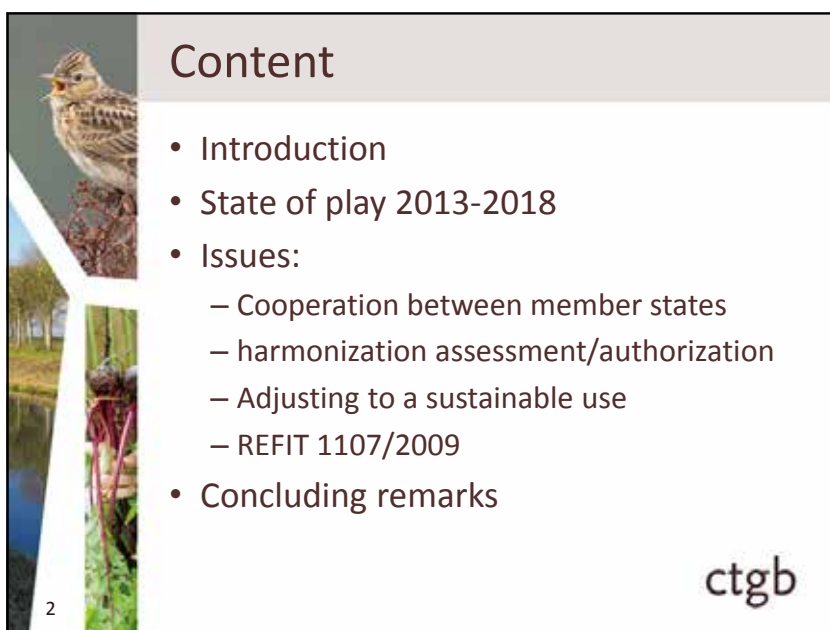
Revised 16th April 2018

***Powerpoint presentation
by Ctgb management (28 February 2018)***

**Powerpoint presentation by Ctgb management
(28 February 2018)**

Presentation:
Johan de Leeuw (chair of the Board)
& Luuk van Duijn (secretary/director)

2nd meeting of the IVC
with the Board and senior management
28 February 2018






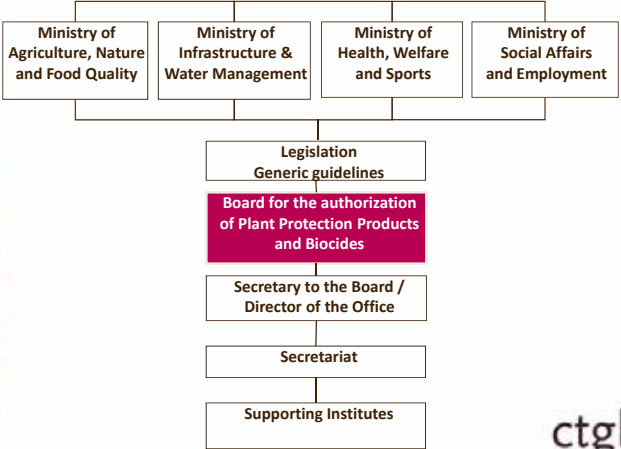
Content

- **Introduction**
- State of play 2013-2018
- Issues:
 - Cooperation between member states
 - harmonization assessment/authorization
 - Adjusting to a sustainable use
 - REFIT 1107/2009
- Concluding remarks

3





Positioning of Ctgb



```
graph TD; M1[Ministry of Agriculture, Nature and Food Quality]; M2[Ministry of Infrastructure & Water Management]; M3[Ministry of Health, Welfare and Sports]; M4[Ministry of Social Affairs and Employment]; M1 --- L[Legislation]; M2 --- L; M3 --- L; M4 --- L; L --- L2[Generic guidelines]; L2 --- B[Board for the authorization of Plant Protection Products and Biocides]; B --- S[Secretary to the Board / Director of the Office]; S --- Sec[Secretariat]; Sec --- SI[Supporting Institutes];
```

4






Legal position, task and role

- The Ctgb is an independent governmental organisation (ZBO, Zelfstandig Bestuursorgaan)
- Governance rules are laid down in the general law on ZBO's
- The Ctgb is mandated to take individual decisions concerning the authorization of PPP's and biocides and to advise the ministers when it deemed this necessary
- Methodology development is not part of the mandate, this is mandated to, ao, the RIVM (state institute for public health and environment)

ctgb

5



The Board 1

- The Board acts within the political responsibilities of 4 ministries: Agriculture, Nature and Food Quality, Infrastructure and Water Management, Public Health and Social Affairs;
- Its tasks, responsibilities and power of decision are laid down by the law;
- The minister is responsible for laying down the guidance documents within which the Board must make its decisions;


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Presentation:

Johan de Leeuw (chair of the Board)
& Luuk van Duijn (secretary/director)

2nd meeting of the IVC
with the Board and senior management
28 February 2018




The Board 2

- The minister can, in certain circumstances, make a specific ruling concerning decisions of the Board.
- However this is embedded in strict rules and the parliament must be informed immediately
- To our knowledge, this happened just once, in 2012.

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The Board 3

- The Board has 9 members;
- Their expertise spans the fields relevant for PPP's and biocides;
- They are nominated by the Board;
- They are appointed by the minister of Agriculture with consent of the minister of Infrastructure and Water Management;

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Presentation:

Johan de Leeuw (chair of the Board)
& Luuk van Duijn (secretary/director)

2nd meeting of the IVC
with the Board and senior management
28 February 2018




Board 4

Leden van het College:

- Ir. J.F. de Leeuw, oa voormalig-SG SoZaWe en voormalig DG LNV, voorzitter
- Prof. Dr. H.J.P. Eijsackers, ecotoxicologie, plv voorzitter
- Dr.ir. E. den Belder, geïntegreerde gewasbescherming
- Prof. Dr. A.P. van Wezel, drinkwaterkwaliteit
- Drs. D.H.J van de Weerd, GGD-arts
- Vacature, chemie
- Dr.ir. R. Houba, arbeidsomstandigheden
- Dr.ir. M. Wolfs, fysische chemie, handhaving
- Dr.ir. W.A.J. de Milliano, planteziektekunde


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Relation Board and Secretariat 1

- The Secretariat is responsible for the assessment of applications, and drafting the advice to the Board;
- The Board discusses this advice and:
 - adopts or rejects the advice, or
 - asks for clarification of certain issues
- The Board is responsible for the final version of the assessment, the reasoning and the decision on authorization
- The director of the Secretariat is responsible for the proper functioning of the secretariat, acts as secretary to the Board and for the minutes of the Board meetings

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The Board 4

- Their fixed term is 4 years, with the possibility of 2 renewals.
- Board members are independent experts

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Relation Board and Secretariat 2

- The Board decides upon the budget, quarterly and annual report (which needs the consent of the ministry of Agriculture) and strategic decisions of the organisation
- The Board supervises the secretariat
- The daily supervision is delegated to the chair of the Board


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Presentation:

Johan de Leeuw (chair of the Board)
& Luuk van Duijn (secretary/director)

2nd meeting of the IVC
with the Board and senior management
28 February 2018



Relation Board and Secretariat 3

- The secretariat is responsible for the assessment and advice to the Board on authorizations
- The Board decides upon (interpretation of) guidances and can develop its own guidance when necessary on its own decision or on advice of the secretariat

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Integrity

- Integrity code for Board, secretariat and external assessors
- Confidentiality
- Possible conflict of interest:
 - public register (additional) offices Board Members
 - duty to report (additional) offices at, and interest in companies by external assessors and staff to secretary/director
- Board Members and staff must take the oath

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Appeals

- Concerned parties can challenge a
- decision of the Board.
- In the Netherlands, concerned parties are not only industry, but also NGO's and others with a legitimate interest.
- NGO's can thus challenge a decision of the Board.

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Disclosure 1

Public unless...

- The decision of authorization is made public simultaneously with the complete assessment report by the office.
- Other documents are disclosed on request, within the legal constraints.

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Disclosure 2

- The European Court decided on two cases last year.
 - One against the Commission (glyfosaat) and one against the Ctgb (neonicotinoids)
 - Ctgb is still waiting for a Dutch court ruling concerning the European Court decision
- A common European guidance for disclosure is needed but not yet finalised


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 - Adjusting to a sustainable use
 - REFIT 1107/2009
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Relevant developments since 2013

1. Biocides
 - Biocidal regulation came into force
 - First European applications in 2015
 - Ctgb interesting partner since The Netherlands has a long history in biocide regulation
 - Steep learning curve, investing in capacity, training personnel, intensive contacts with ECHA
 - First to finalize union Authorizations
 - Growth from 20% to 40% of the Ctgb portfolio

LDU

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Relevant developments since 2013

2. Plant protection products:
 - Regulation came into force in 2011
 - Gradually changing the rules (guidances) and the application of the rules
 - Renewal process ai's is a heavy burden and predictability is low

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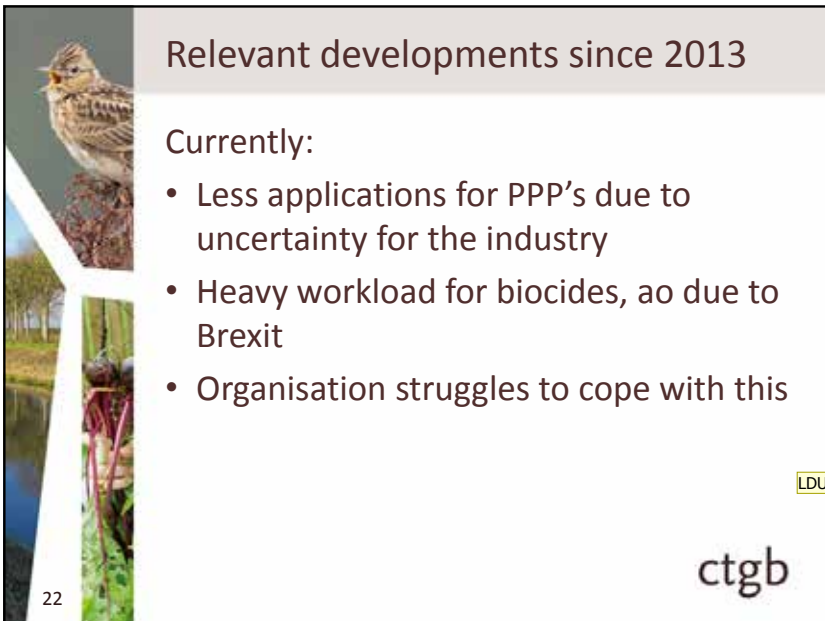
Relevant developments since 2013

Organization

- Growth
- Professionalization
- Improved information services (internal and external)
- Stakeholder management

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Relevant developments since 2013

Currently:

- Less applications for PPP's due to uncertainty for the industry
- Heavy workload for biocides, as due to Brexit
- Organisation struggles to cope with this

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European cooperation

- On expert level the Ctgb is strongly embedded in the European networks
- In the field of biocides, ECHA has a strong organizational role, which works OK
- Nevertheless the Ctgb organized a “directors conference” to discuss organization matters (forecasting and planning)

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European cooperation

- In the field of PPP's EFSA has a role restricted to ai approval and guidance development
- No coordination on PPP's
- On zonal level, the Ctgb took the initiative for a zonal directors conference
- Aim: harmonize regulation and guidance interpretation, solve issues were necessary

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Content

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Harmonization PPP's

- Most discussions focus on ecotox/birds and mammals
- Most deviations/rejections for CMS- en MR-applications are on BM
- Not on national specific elements
- Complex guidance aiming at protection of focal species
- In practice: focal species are defined nationally

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Harmonization

- To avoid discussions, more and more issues are transferred from core to national addendum though directors decided to stop this
- “convergence” procedure was decided upon by directors
- Working group on team manager level
- Results to be seen

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Harmonization biocides

- BPR is a firm base for harmonization
- ECHA plays its role pretty well
- However, due to workload, a.i. approval decisions leave often on several issues open
- Leaving the burden of harmonization of applications for member states

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Bridging the gap

- Biocidal a.i. approval and the approval for plant protection are completely separate systems
- Meaning the industry faces high costs when it wants to cover both fields
- Especially on disinfection this means that a.i.'s for agriculture (glass houses) are not available
- Ctgb will start a pilot with EFSA and COM to bridge this gap

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Sustainable use

- There is a strong drive for sustainable use
- Digital farming is a major drive for innovation
- It is clear that the authorization system must adapt to these developments

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Key points REFIT 1107/2009

- The Regulation has a positive impact
- Key points for improvement:
 - Preconditions compatible with IPM
 - Low risk: 'approval unless proven not safe'
 - Arbitration by Competent Authorities
 - Update rather than integral assessment a.s.
 - Simplification of risk assessment methods
 - Fixate framework for a.i. and ppp after a.i. approval

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- **Concluding remarks**

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Concluding remarks

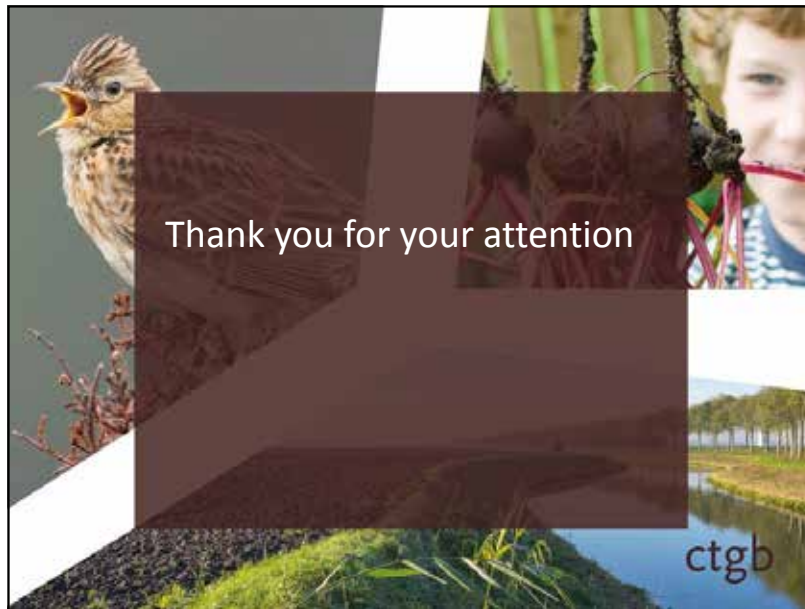
- Both regulations are implemented but both practices are still developing
- International cooperation and harmonization are “learning by doing”
- Relevant questions:
 - how much room must a guidance leave for national interpretation
 - how to organize convergence between member states

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Presentation:
Johan de Leeuw (chair of the Board)
& Luuk van Duijn (secretary/director)

2nd meeting of the IVC
with the Board and senior management
28 February 2018



Presentation:
Ivonne van Geerenstein (Mgr. Business Operations)
Nicole van Straten (Mgr. Scientific Assessment and Advice)

2nd meeting of the IVC
with the Board and senior management
28 February 2018





Ctgb organisation


Changes since 2013:
 Organisational change (growth & chart)

Personnel policy development:


- Revision of Personnel policy
 - *Revision of Integrity policy*
- Knowledge policy (new and under construction)

Other:

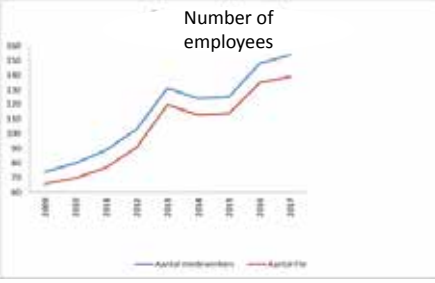
- *Strategy and mid term planning*
- *Information policy (revision)*
- *Quality policy (new + ISO 9001:2015)*

3



Organisation growth




Employees

01-01-2013:	103
31-12-2017:	154

50% increase compared to 2013

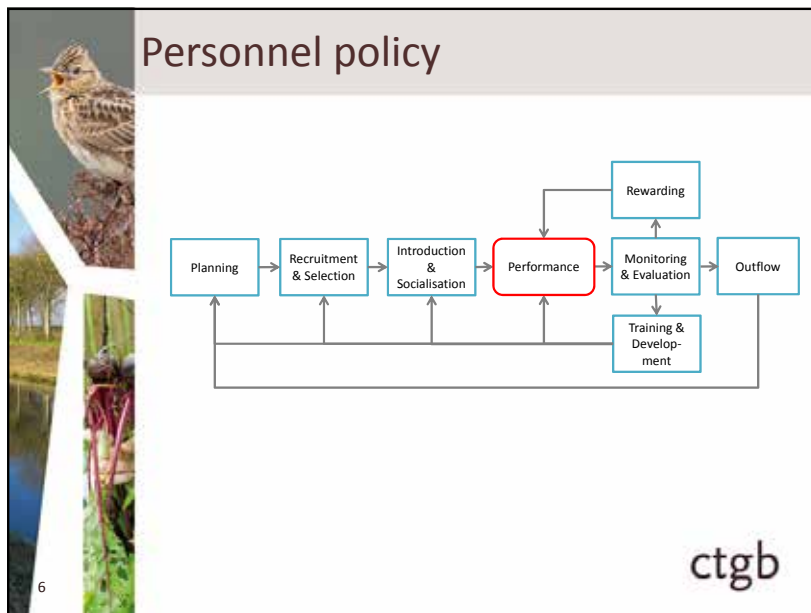
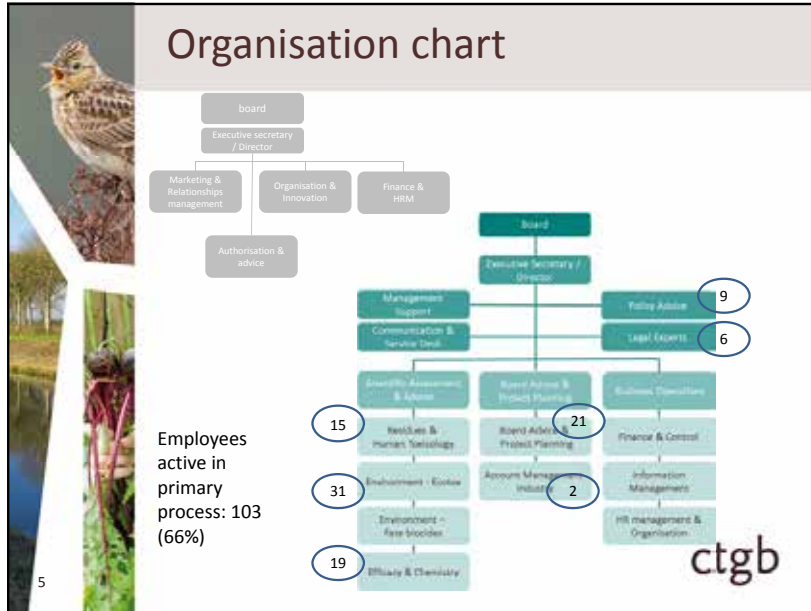
male; 57 (37%) / female; 97 (63%)



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Presentation:
 Ivonne van Geerenstein (Mgr. Business Operations)
 Nicole van Straten (Mgr. Scientific Assessment and Advice)

2nd meeting of the IVC
 with the Board and senior management
 28 February 2018






Integrity policy

- New governmental integrity code
- Integrity code for Board members, employees and external experts.
- Duty to report (once a year) possible conflicts of interest.
- CV's of the Board members are published on the Ctgb website.


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Personnel policy - Training & Education

Financial budget spent 2013 – 2017:



Year	Budget (Euro)	Realisation (Euro)
2013	~250,000	~150,000
2014	~250,000	~150,000
2015	~250,000	~150,000
2016	~250,000	~150,000
2017	~250,000	~150,000


Hours spent 2013 – 2017:



Year	Budget (hours)	Realisation (hours)
2013	~15,000	~10,000
2014	~15,000	~10,000
2015	~15,000	~10,000
2016	~15,000	~10,000
2017	~15,000	~10,000

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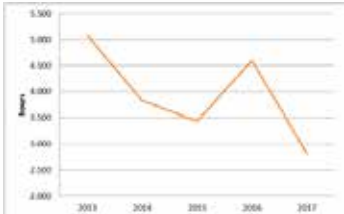
8



Personnel policy – external consultants


Strategy for use of external scientific consultants adjusted:

- strive for 100% internal coverage of capacity instead of 95%
- use external scientific consultants for
 - peaks in workload
 - unforeseen employee leave or absence
 - highly specialised expertises
- External consultants: RIVM, NVWA, Linge, CRL, WUR
- Service Level Agreements (5 years) Cooperation Agreement (1 year)
- Policy documentation available as well as yearly evaluations



Year	Value
2003	5.000
2004	3.500
2005	2.500
2006	4.000
2017	2.000

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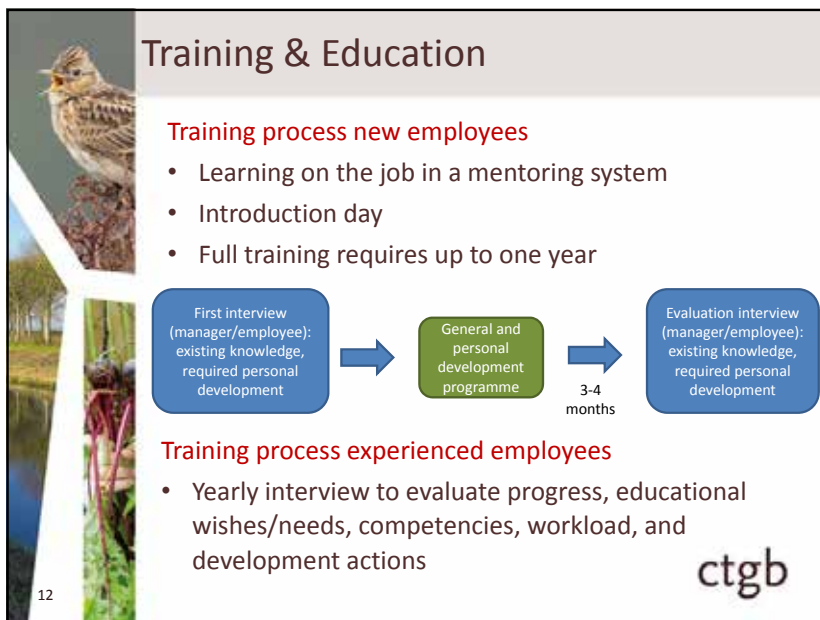
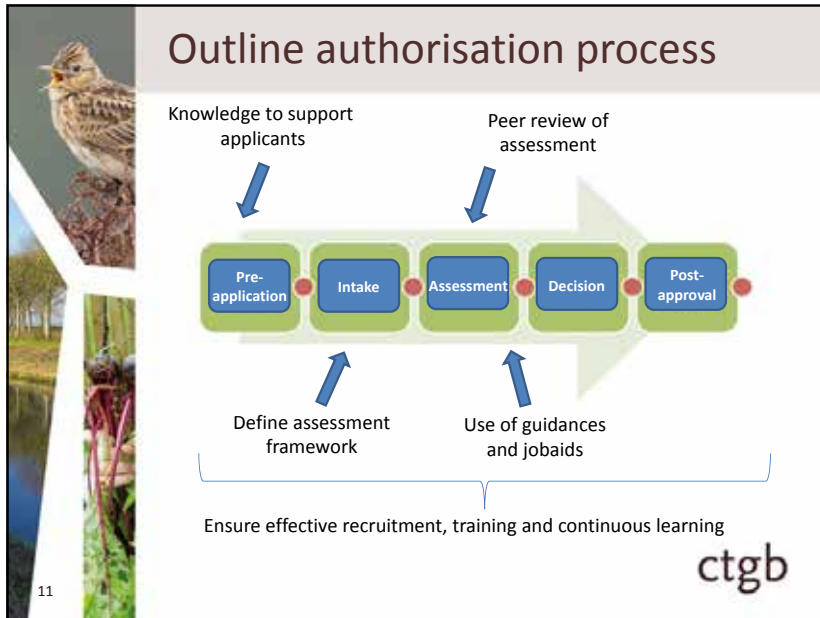
Training & Education


Recruitment & staffing process

- All scientific assessors have at least MSc degree or BSc degree with academic thinking level and/or broad experience (e.g. chemistry, efficacy)
- All in house human toxicologists are trained or in training to become European Registered Toxicologist (ERT).

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Training & Education

Up to date expertise and knowledge


- Participating and presenting in internal or external (EU) workshops, conferences or courses
- Workshops in the field to experience daily practice
- Participation in guidance development:
 - Methodology development by strategic partners RIVM and NVWA
 - Reviewing and applicability check by Ctgb
- Occasionally contribute to scientific publications (but no primary goal)
- Knowledge management policy is under construction, supplementary to HRM policy

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Scientific process

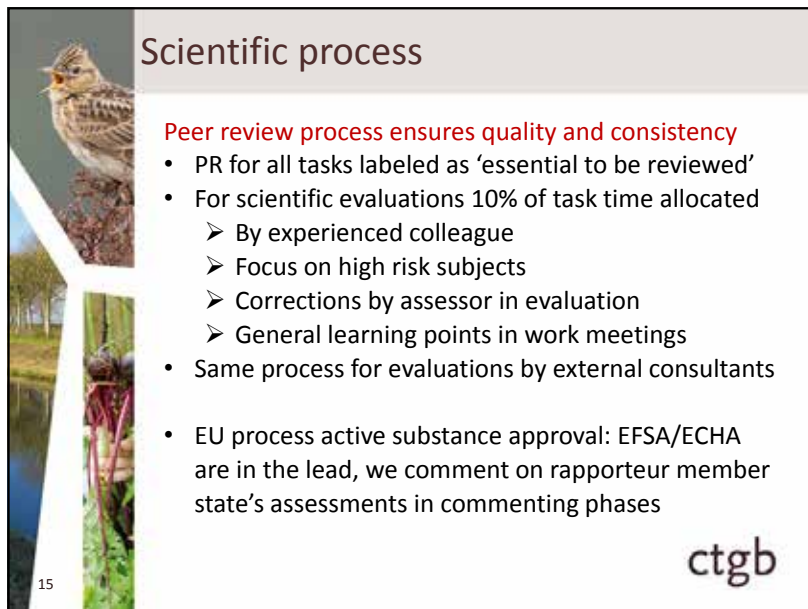
The assessment framework cycle



- Facilitates the implementation of ALL new assessment framework (AF) items
- Two AF coordinators, for process and technical items
- Up to date evaluation manuals (chemicals and biopesticides) and registration manual
- Easy web based access for applicants and assessors
- Internal working procedures laid down in jobaids

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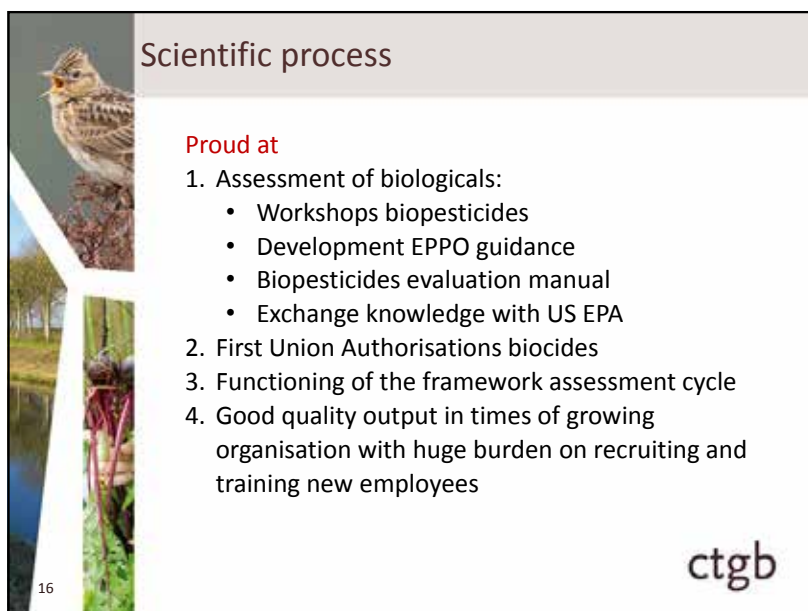
Scientific process

Peer review process ensures quality and consistency

- PR for all tasks labeled as 'essential to be reviewed'
- For scientific evaluations 10% of task time allocated
 - By experienced colleague
 - Focus on high risk subjects
 - Corrections by assessor in evaluation
 - General learning points in work meetings
- Same process for evaluations by external consultants
- EU process active substance approval: EFSA/ECHA are in the lead, we comment on rapporteur member state's assessments in commenting phases

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Scientific process

Proud at

1. Assessment of biologicals:
 - Workshops biopesticides
 - Development EPPO guidance
 - Biopesticides evaluation manual
 - Exchange knowledge with US EPA
2. First Union Authorisations biocides
3. Functioning of the framework assessment cycle
4. Good quality output in times of growing organisation with huge burden on recruiting and training new employees

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***IVC 2018 follow up on recommendations
from the visitation in 2013***

**IVC 2018 follow up on recommendations from
the visitation in 2013**

Follow-up on recommendations from the visitation in 2013

The report of the first International Visitation Committee included among other aspects a series of 29 recommendations for improvements (see:report on the international visitation of the CTGB Board, July 2013). On 18 January 2018 the Ctgb provided the members of the second International Visitation Committee with clarifications of those recommendations that were not or only partly implemented. It appeared that during the last 5 years 17 recommendations were accepted and implemented, 1 recommendation was accepted but not yet implemented, 4 were partly accepted and 7 were not accepted.

In the table below the respective recommendations that were not accepted or partly accepted are listed, followed by the formal response from the Ctgb and the subsequent comment made by the IVC 2018 made prior to its visitation. The numbering follows that of the 2013 report. The 17 recommendations which were accepted and subsequently implemented are not included in the table. The table content was very useful for the preparation of the visitation and during the actual visitation.

Recommendation 4.2.1

IVC 2013:

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 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.

Formal response of the Ctgb:

(Quote) "Recommendation not adopted. Regarding product authorization, Ctgb does publish the decision of the Board, that includes 'the formal decision' (in Dutch) and 'the assessment report' (in English). Modifications by the Board of proposed Decisions are traceable for internal use as these are archived in the Ctgb's Document Management System. In DMS you'll find the agenda, a summary on findings and key discussion points, a written record of the discussion in the Board meeting (in Dutch), 'the formal decision' (in Dutch), 'the assessment report' (in English) and the history of these documents.

The structure of the Ctgb differs from the European structure with a formal separation of risk-assessment performed by experts and risk management by government officers. In the Ctgb

the risk assessment is also performed by experts, but the management decision is taken by the Board which consists of experts in the relevant fields but with a broad expertise in e.g. public health of occupational hazards. The Board scrutinizes the assessment report (in fact performs a "peer review") adopt it, asks for clarification or asks for new information and makes its decides upon that and upon the advice of the secretariat on authorisation, amendment or refusal. Therefore, only the finalised assessment report is the report on which the assessment report is the report on which the

Report decision upon authorisation is based. All other reports are drafts, not meant for publication. In cases that the determining factors are considered relevant for the general public the Board communicates the rationale of its decisions in a press release related to the decision of product authorization. This may concern an explanatory note on non-authorization, hazard mitigation, early adoption of developments in the assessment framework, or modifications of proposed Decisions. The press releases are drafted in Dutch as the target readers are considered pesticide users and Dutch NGO' s and the Dutch public."

Comment IVC 2018

The IVC is of the opinion that the essence of separating risk assessment from risk management is that the latter considers in its decision making additional equally valid elements such as economic, cultural, religious/ethical and political consequences. Separating these equally relevant risk management components from the science-based risk assessment makes the process transparent.

Recommendation 4.2.2

IVC 2013:

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.

Formal response of the Ctgb:

(Quote) "Recommendation not adopted. The records on internal discussions and internal discussion documents are not drafted in English, since the spoken and written language at the Ctgb is Dutch. Regarding product authorization, Ctgb does publish the decision of the Board, that includes 'the formal decision' (in Dutch) and 'the assessment report' (in English)."

Comment IVC 2018

The request for translation into English of those elements of Board meeting minutes that concern authorizations and the part of meetings of scientific staff meetings that deal with risk assessment

is based on the need to be able to evaluate the interference between both. In case of full transparency that need is less urgent.

Recommendation 4.2.3.

IVC 2013:

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.

Formal response of the Ctgb:

(Quote) "Recommendation not adopted. The structure of the Ctgb differs from the European structure with a formal separation of risk-assessment performed by experts and risk management by government officers. In the Ctgb the risk assessment is also performed by experts, but the management decision is taken by the Board which consists of experts in the relevant fields but with a broad expertise in e.g. public health or occupational hazards. The Board scrutinizes the assessment report (in fact performs a "peer review") adopt it, asks for clarification or asks for new information and decides upon it and decides upon the advice of the secretariat on authorisation, amendment or refusal. Therefore, only the finalised assessment report is the report on which the decision upon authorisation is based. All other reports are drafts, not meant for publication. Modifications by the Board of proposed Decisions are traceable for internal use as these are archived in the Ctgb's Document Management System. The final decision of the Board published on the Ctgb website, incorporates the combined result of risk assessment and risk management."

Comment IVC 2018

Taking note of the strong preference of the Board to decide both on risk/safety assessment and risk management, full transparency of the process seems to be the only solution to enable distinguishing one from the other. This implies that minutes of decision making meetings should provide detailed insight into discussions and distinctiveness in recognising management from scientific arguments. In order for non-Dutch- language-understanding professional experts to follow and understand such discussions in written minutes, the need for translation into English seems inevitable.

Recommendation 4.3.1.

IVC 2013:

The IVC respectfully suggests and recommend 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 Chairperson and the Secretary/Director be described with precision, thereby avoiding any uncertainty or ambiguity with regard to their responsibilities and mandates.

Formal response of the Ctgb:

(Quote) "Recommendation accepted but not yet adopted. Ctgb accepted this recommendation and took up the recommended revision of both decrees together with the revision of 'the Decree on the administrative regulations for the authorization of plant protection products and biocides Ctgb 2007' ('Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007'). The three decrees elaborate on the role of Ctgb within product authorisation in the Netherlands for plant protection products and biocides. The content of these decrees has got outdated after the publication of the Plant Protection Products Regulation 1107/2009 and the Biocidal Product Regulation 5268/2012. Despite considerable effort, Ctgb was yet not able to finalize the revision of these decrees."

Comment IVC 2018

The IVC has taken note of the delay and expects the requested revision to be adopted and implemented before the end of 2018.

Recommendation 4.4.2.

IVC 2013

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

Formal response of the Ctgb:

(Quote) "Recommendation adopted for human toxicologists

New contracted scientific assessor's human toxicology not necessarily have a degree as European Registered Toxicologist (ERT). When not, these employees are asked as part of the personal development plan to achieve this registration aside from their work at Ctgb.

Ctgb states in its annual report among others the number of human toxicologists with an ERT registration."

Comment IVC 2018

The IVC sees no reason why the ERT status is limited to human (mammalian) toxicologists, instead of all fields of toxicology, in particular environmental toxicology.

Recommendation 4.4.3.

IVC 2013:

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 Ctgb be made publicly available on either the Ctgb website or that of the contracting organisation, preferably in the harmonised EU format.

Formal response of the Ctgb:

(Quote) "Recommendation not adopted. Regarding the recommendation to publish the CVs of the Board, the management and the employees on the Ctgb website, the Ctgb holds the position to publish only the CVs of the Board and the director of the Board Secretariat on the website. These are the persons with a formal mandate in assessment and decision. All other persons have a permanent, in principal fulltime position and are not allowed to have any other function with a possible conflict of interest. Despite the need of transparency, the Ctgb chooses therefore to respect the privacy of the employees and to ensure that confidential information is not traceable to persons. This is based on Dutch privacy law. Based on these considerations, it was decided not to publish the CVs of the employees on the website. To promote transparency, Ctgb does publish in the annual report for the different teams of scientific assessors an overview of the education level of the academic staff. Internally, Ctgb monitors the Declarations of Interest of its employees on a yearly basis."

Comment IVC 2018

The IVC considers the decision to publish only the CVs of individuals with a formal mandate in assessment and decision making as inadequate and lacking transparency. As a minimum the level of education, area of expertise, and years of experience (both before and at Ctgb) of the scientific risk assessors should be made accessible.

Recommendation 4.4.5.

IVC 2013

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).

Formal response of the Ctgb

Recommendation (partially) adopted. Ctgb strives for 100% internal coverage of the required capacity or even slight overcapacity, this to cover uncertainties caused by external factors, but also internal factors such as employee leave or absence, which easily leads to a (temporary) internal capacity shortage. However, to be just, Ctgb yet applies an internal coverage of the required coverage of approx.96% and uses a 4% external capacity to cope with peaks in capacity demand. In addition Ctgb hires external capacity restricted to specialized and innovative areas of expertise not available within the Ctgb.

Ctgb endeavours settlement of strategic alliances with knowledge institutes that have complementary knowledge on specialized and innovative areas of expertise not (yet) available within Ctgb. These alliances aim at long term cooperation, mutual commitment, knowledge exchange and transparency. Examples are alliances with RIVM and NVWA (Netherlands Food and Consumer Product Safety Authority).

Comment IVC 2018

The IVC takes note of the outsourcing policy of the Ctgb and understands the difficulties and challenges of the variable workload. Nonetheless, thriving to achieve the necessary expertise, disciplines and capacity in house to cope with this workload should continue.

Recommendation 4.4.6.

IVC 2013

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.

Formal response of the Ctgb:

(Quote) "Recommendation not adopted. The Ctgb management recognized the idea to introduce a vertical differentiation in role descriptions within the scientific assessors' teams.

In 2015 therefore, an exploration was started of further differentiation of the role descriptions within the primary process. In this process external experience and advice was hired from the Ministry of the Interior and Kingdom Relations. After advice and broad internal consultation, it was decided not to introduce a promotion grade with the argumentation that the introduction of a senior role would require a clear differentiation in tasks, which was considered not convenient to the work and work processes at Ctgb. Concentration of more senior tasks, yet placed out at different members of the team, in one senior role, would reduce the attractiveness of the job of many others. Whereas distribution of tasks from the team leader to a senior role, may create ambiguity.

The idea however to reward employees for specific expertise, skills and talents, is not abandoned. Without the introduction of a senior role, Ctgb explores the possibilities to assign to the standard role profile specified tasks, to offer employees an opportunity to broaden their job and fully utilize their talents."

Comments IVC 2018

The IVC has taken note of this management policy. It needs more information and elaboration in order to take a position on this management decision.

Recommendation 4.4.7.

IVC 2013

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 Master's or PhD qualifications.

Formal response of the Ctgb:

(Quote) "Recommendation partially adopted. Recently, Ctgb's HRM policy has been reviewed and renewed. In the HRM policy general principles are defined on training and education. The HRM policy document does not explicitly demands the prioritization of the education and training of scientific assessors that do not have a masters or PhD qualification. Education and training of all employees however, is covered in a tailor-made personal development plan that is drafted with input of the team leader on employee performance and required expertise. We

are convinced that with this approach in an adequate manner priority be given to the improvement of the skills of all scientific assessors."

Comment IVC 2018

The IVC understands and appreciates the renewed HRM policy. It needs more insight in order to define its position on this issue.

Recommendation 4.4.8.

IVC 2013

It is 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 all scientific assessors have the opportunity to maintain their expertise and be conversant with relevant developments in science and technology.

Formal response of the Ctgb:

(Quote) "Recommendation partially adopted. Ctgb recognizes that time allocated to scientific assessors for review of scientific literature and participation in symposia and congresses is important to maintain their expertise and keep abreast of new developments. Scientific assessors, project leaders, policy advisors and account managers are given the opportunity to maintain their expertise and be conversant with relevant developments. For this time is allocated to the experts. Whenever possible or relevant, Ctgb employees will use their attendance to give a presentation."

Comment IVC 2018:

The IVC considers the Ctgb response as adequate and in line with the recommendation of 2013, provided that the time allocated serves the purpose. This will be addressed during the visitation.

Recommendation 4.4.11

IOVC 2013:

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.

Formal response of the Ctgb:

(Quote) "Recommendation partially adopted. Given the role and position of the Ctgb, writing scientific papers is no primary goal. The Netherlands has chosen to separate methodology development from the executing task in assessments. Nevertheless, we assist the RIVM in methodology development and upon request we collaborate with EFSA and ECHA during the process of new guidance development. In this context Ctgb employees review and comment on the development of assessment methods and on procedural and technical assessment frameworks. Scientific assessors and other staff occasionally will acquire a publication as offspring of a presentation on a symposium or congress. Scientific assessors participate in the 'regular' technical expert meetings at EU level and in some cases also to more general meetings. As direct result of our aim to promote European harmonisation, Ctgb organized several workshops with participants from all Member States, lectured by Ctgb scientific assessors, project leaders and legal advisors, such as: A workshop on efficacy assessment of low risk substances as starting point of the development of new EPPO -guidance; A lawyer workshop; A visit to US Environmental Protection Agency (EPA), exchanging expertise on the assessment of biological products. Expertise that Ctgb applies in the assessment of biological products in Europe was included in the development evaluation manual biopesticides V1.0."

Comment IVC 2018:

The IVC is of the opinion that the extraneous external initiatives are a very positive approaches to broaden the scientific scope of the scientific staff. From the response it is not (yet) clear whether these activities are included in the annual workplan, personal activity plans or *ad hoc* decisions. An indication that scientists have 'room to manoeuvre' in selecting extraneous, yet totally transparent activities, would be appreciated.

Recommendation 4.6.3

IVC 2013

The IVC 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.

Formal response the Ctgb:

(Quote) "Recommendation not adopted. Aspects of evaluations are reviewed by a colleague. The overall evaluation that ultimately becomes Appendix II to authorisation Decisions is peer viewed by one Project leader, where highlights are collected for lay-on notes. No overall analysis that needs attention. At the moment a systematic approach where all assessments and decisions are screened, is developed and will be implemented second half of 2018. Moreover, in cooperation with the legal department and the department of scientific advice and project management periodic reviews of decisions in relations to appeal procedures are performed and discussed."

Comment IVC 2018

The IVC requested a peer, confirmative review of the (draft) Decisions of the Board by the project leader, Team leader and the scientific assessors involved prior to making the final decision. From the response from the Ctgb, the IVC concludes that feedback from the scientific experts on the final risk management (including risk assessment) Decision is not considered. The IVC regrets this policy, the more so as in general full transparency is not the strongest quality of the Ctgb.

Recommendation 4.6.4

IVC 2013

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.

Formal response the Ctgb:

(Quote) "Recommendation not adopted. The Ctgb participates in the EU process for approval of active substances. This process includes an extensive peer review process, so member states peer review the work performed by the rapporteur member state. The same concerns for the development of guidance, where Ctgb employees review the concept guidances in their field."

Comment IVC 2018:

The IVC appreciates the participation at EU level. However, new approaches and other innovations happen not necessarily in the EU alone. The IVC would like to find the Ctgb amongst the frontrunners rather than in the peloton.

CV format at Ctgb

CV format at Ctgb

General Expert Information

Surname / Last Name

Forename(s) / First Name(s)

Titel(s)

Function

Competencies

Choose at least one field of competence

Plant protection products:

- Plant protection products (chemical substances)
- Plant protection products (biological substances)
- Phy-chem properties of plant protection products (including analytical methods)
- Environmental RA of plant protection products (fate and behaviour in water, soil and air)
- Eco-toxicological effects of plant protection products
- Human and mammal toxicology of plant protection products
- Residues (and RA to consumers) in relation to plant protection products
- Efficacy assessment of plant protection products
- Authorisation procedures for plant protection products

Other competencies can be listed below

Biocides

- Biocides (chemical substances)
- Biocides (biological substances)
- Phy-chem properties of biocides (including analytical methods)
- Environmental RA of biocides (fate and behaviour in water, soil and air)
- Eco-toxicological effects of biocides

- Human and mammal toxicology of biocides
- Residues (and RA to consumers) in relation to biocides
- Efficacy assessment of biocides
- Authorisation procedures for biocides

Other competencies can be listed below

Other competencies

-
-
-
-

Additional information

Knowledge of languages:

Languages in which you feel comfortable to communicate and work:

- English
- German
- French
- Spanish
-
-

Education

University degree(s), University college degree(s) or equivalent

Make an entry for each degree completed, i.e. each degree program leading to a qualification, starting with the most recent.

Dates

Degree

Training

List participation in relevant training courses, symposia, congresses, etc.

Dates

Degree / Activity

Professional experience

Number of years of relevant professional experience:

Present and past professional positions held:

Make an entry for each position, starting with the most recent.

Dates	Professional position
	<i>State job title, main activity, name and business location of the employer. State also job-related participation in working groups and scientific networks.</i>

Specific curricular information:

State here any other information, which you think relevant.

Listing of relevant Publications:

- 1. List your publications in peer reviewed journals (starting with the most recent)*

2. *List the scientific output from working groups and scientific networks that you participated in as employee of Ctgb*
 3. *List output such as lectures at (scientific) symposia and congresses*
-
-

Dol format at Ctgb

Dol format at Ctgb

Formulier melding nevenwerkzaamheden

Met dit formulier kun je nevenwerkzaamheden melden.

Let op: we gaan er van uit dat je het uitvoeren van nevenwerkzaamheden, vóór je dit formulier invult, hebt afgestemd met je leidinggevende!

Voor een toelichting [klik hier](#)

- Verklaring*
 - Ondergetekende verklaart hierbij dat hij/zij op de datum waarop deze verklaring is ingevuld géén nevenwerkzaamheden verricht en verklaart tevens wanneer nevenwerkzaamheden, zoals bedoeld in het 'Besluit Nevenwerkzaamheden', verricht gaan worden, deze voordat feitelijke uitvoering plaatsvindt te melden
 - Ondergetekende verklaart hierbij dat hij/zij nevenwerkzaamheden (geheel of gedeeltelijk) binnen werktijd dan wel buiten werktijd verricht dan wel wil gaan verrichten

- **Gegevens medewerker:**

- Naam en voorletters*

- E-mailadres

- Geboortedatum*

 DD MM JJJJ

- Functie*

-

-

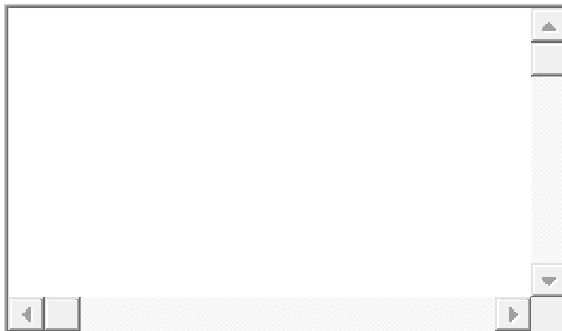
- **Gegevens over de nevenwerkzaamheden**

- Functie, globale omschrijving van de aard van de werkzaamheden en de naam van de betreffende organisatie:

- **Functie 1**

- Functie*

- Werkzaamheden



- Organisatie*

- Datum ingang

 DD MM JJJJ

- Einddatum

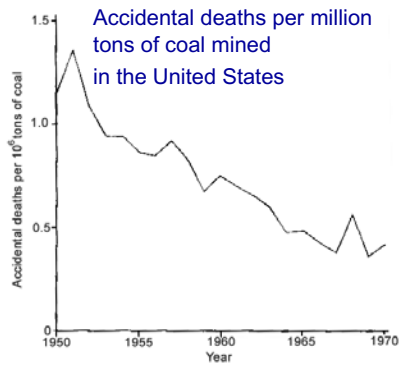
 DD MM JJJJ

- Uren per week binnen werktijd

- Betaald?
 - ja
 - nee
- Tweede functie melden?
 - Ja
-
- Heb je voor de uren binnen werktijd reeds buitengewoon verlof?
 - Ja
 - Nee
-
- Heb je het formulier compleet ingevuld?*
- Nee
- Ja

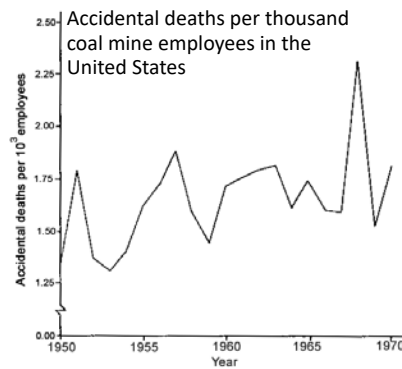
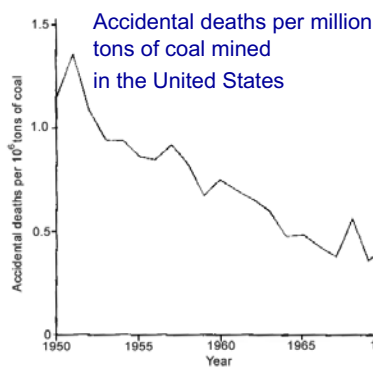
Choosing a Measure of Risk

Is coal mining getting safer? It depends on which measure you choose.



Choosing a Measure of Risk

Is coal mining getting safer? It depends on which measure you choose.





3

List of documents requested

List of documents requested

Documents provided By Ctgb

1) General		
Title/topic	Provided on	Provided by
Process of active substance approval (EU document)	August 2018	J.H.M. Kortekaas
Annual report 2017 (in Dutch)	July 2018	L.P. Van Duijn,
English summary Annual report 2017	July 2018	L.P. Van Duijn,
Ctgb Organogram	July 2018	J.H.M. Kortekaas
Questions to Ctgb staff - June	June 2018	J.H.M. Kortekaas
Start-up of directors' meetings for CA's involved in the authorization of biocides and plant protection products- related documents a) Rules of procedures b) Minutes TC March 2018 c) Draft agenda of the 7th MSCA Directors' meeting 11 and 12 October 2017, ECHA, Helsinki	June 2018	J.H.M. Kortekaas
Access to operations manuals and SOPs prepared for use by scientific staff and dossier managers	March 2018	J.H.M. Kortekaas
Internal and external scientific peer review processes and evaluations	March 2018	J.H.M. Kortekaas
Information on Ctgb "Knowledge Partners"	March 2018	J.H.M. Kortekaas
Overview of Evaluation framework/Implantation cycle	March 2018	J.H.M. Kortekaas
IVC Report 2013	February 2018	Made available to IVC in DMS
ISO Quality Management Principles (ISBN 978-92-67-10650-2, ISO 2015)	January 2018	Herman Koeter
2) Board activity		
Title/topic	Provided on	Provided by
Discussion/disagreements between Board and secretariat	July 2018	L.P. Van Duijn
Policy and operational guidance prepared for the Board	April 2018	J.H.M. Kortekaas

Access to Minutes of the Board	April 2018	J.H.M. Kortekaas
CV board members	April 2018	J.H.M. Kortekaas
3) DARs and CARs		
Title/topic	Provided on	Provided by
Access to dossiers, DARS and CARs for active substances and products, both PPP and BP, in the DMS, where the IVC selected a range of samples, using pre-defined criteria,	February 2018	Made available to IVC in DMS
5) Legal aspects		
Title/topic	Provided on	Provided by
'Rules of thumb' concerning access to environmental information (based on Court's decision C-244/14)	June 2018	Made available to IVC in DMS
Access to procedures for dealing with formal complaint	March 2018	J.H.M. Kortekaas
Overview of the Ctgb input in the REFIT process	March 2018	J.H.M. Kortekaas
6) Scientific staff		
Title/topic	Provided on	Provided by-
Access to Declarations of Interests	May 2018	J.H.M. Kortekaas
Overview scientific publications within the teams of scientific assessors and project leaders.	May 2018	J.H.M. Kortekaas
Access to minutes of scientific staff (scientific and procedural)	April 2018	J.H.M. Kortekaas
Participation to development/updating of EU guidance	April 2018	J.H.M. Kortekaas
- Employees list by Unit/Team - CV - Description of functions and responsibilities	March 2018	J.H.M. Kortekaas
Detailed organisation chart of scientific staff and management	March 2018	J.H.M. Kortekaas
Access to documentation on evaluation criteria, including staff training policies	March 2018	J.H.M. Kortekaas

Time spent by new employees learning on the job (Excel file)	March 2018	J.H.M. Kortekaas
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BACKGROUND DOCUMENTS

Documents and links relevant to the scientific assessment work of Ctgb made available in the DMS, in particular documents from:

ECHA

EFSA

EU legislation on BP

EU legislation on PPP

ISO Quality Management Principles (ISBN 978-92-67-10650-2, ISO 2015)

Sanitised dossier evaluations

“Summary of all 11 dossiers evaluated by the IVC 2018”

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F. BIOCIDAL PRODUCT..... - 13 -

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Comments on assessment reports Active substances

A. Biocidal Active substance

Common Assessment Report (CAR) Biocide active substance and products (Product Type 14 rodenticide)

The original authorization, Assessment Report, was by Italy (RMS). Identified as a candidate for substitution, in view of its meeting the criteria for Persistence, Toxicity and Bioaccumulation (PTB) and the conclusion that A. poses an unacceptable risk for primary and secondary poisoning of birds and other non-target mammals. However, as an exceptional case, it was decided that benefit should take precedence over risk and the Commission proposed inclusion in Annex 1 to Directive 98/8 EC. The Standing Committee on Biocidal Products agreed and added it to Annex 1 but with strict Risk Mitigation Measures (RMMs) to reduce environmental exposure and the risk to non-target species.

NL was the RMS for the renewal of the active substance to be considered by ECHA.

Criteria and comments

1. Compliance with legislation and guidance documents

The original documentation is trackable, including comments made to RMS Italy from eight MS including NL.

The re-evaluation assessment report prepared by NL (jointly with Italy) for renewal seems to be in compliance with the adopted EU guidances and the Biocide Legislation.

The conclusion is logical and supported by the earlier documentation and re-evaluation of the major issues.

2. Clarity and comprehensibility of the Scientific Opinion

Clarity and comprehensibility of the Assessment report is high.

There is a clear and informative issues table in which NL addresses the comments of the different CMS. The argumentation from NL is quite robust with clear and strong reasons where comments are not accepted.

ECHA adopted the positive recommendation of the Standing Committee on Biocidal Products including strong risk mitigation measures (RMM) and instructions to authorising national competent authorities for tight restrictions of public and professional use of authorised products.

The report was finalised (but no indication as to how it had been modified after the original submission).

3. Weight of evidence considerations.

The conclusion is that the earlier risk evaluation is still applicable for the renewal though it is not possible from the documents to identify whether this evaluation was made by the applicants or by the evaluator

Assumptions and uncertainties are identified but are assumed that they would be effectively reduced by the imposition of restrictive and extensive RMMs

4. Evidence of recognition and acceptance by ECHA, EU member states.

Clearly the leading documents have been accepted by ECHA and the involved MS.

5. Level of adequateness of the response to comments, questions and suggestions from Member States' experts

Documented comments from other MS appear to have been considered, some accepted and some not according to clear scientific arguments.

6. OVERALL STATEMENT A. BIOCIDAL ACTIVE SUBSTANCE

The overall impression was that the different roles of Ctgb as (rapporteur) RMS and (commenting) CMS were conducted effectively, clearly and, as far as could be understood, with scientific balance and in general, good documentation.

B. Microbiological Pest Control Agent

Draft Renewal Assessment Report (dRAR), Plant Protection Product representative formulations

Microbial pest control agent (MPCA). Fungicide for outdoor uses (seed dressing) also allowed in organic farming. The Netherlands is Rapporteur Member State (RMS), Denmark DK is Co-RMS (originally evaluated by SE in the first round of approvals).

Criteria and comments

1. Compliance with legislation and guidance documents.

Draft Renewal Assessment Report (dRAR) prepared by the NL.

Comments on the dRAR received from the Co-RMS DK and other MS. EFSA peer review was organized. EFSA conclusion was published

The re-evaluation conducted by the Ctgb seems to be in compliance with the currently adopted EU guidance documents and PPP legislation.

During the peer review data gaps were identified: analytical methods for the metabolite, refinement of exposure and risk assessment of the metabolite on human health and non-target organisms.

Significant amount of additional data was required according to the EU data requirements laid down in the Commission Regulation 283/2013 as a conclusion of EFSA peer review.

NL as the RMS prepares an addendum to the dRAR, work is ongoing.

2. Clarity and comprehensibility of the Scientific Opinion.

The areas of concern were clearly presented in the dRAR with the main issues highlighted and discussed during the peer review

Further data requirements are clearly presented and motivated both in the dRAR and in the answers given on the comments from other MS during the peer review.

3. Weight of evidence considerations.

Further data requirements are clearly presented and motivated both in the dRAR and in the answers given on the comments from other MS during the peer review.

Conclusion: low risk substance.

The case is still open and the zonal product evaluations of the representative formulations are pending.

4. Evidence of collegiate feedback and/or peer reviews.

The reflections of the Ctgb on the comments of Co-RMS, other MS and EFSA appear well founded, scientifically sound and clear.

Significant amount of additional data was required as a conclusion of EFSA peer review.

All correspondence with the Notifier, other MS and EFSA is clearly documented and archived and well traceable in the DMS of the Ctgb.

There is evidence of internal peer review at the Ctgb in the form of e-mail discussions as well as in the Board documentation, which are transparently recorded in the DMS of the Ctgb.

5. Level of consistency and coherence.

The case is still open during the IVC evaluation 2018: additional data was required to be submitted and evaluated as a follow-up of the EFSA peer review.

The conclusions drawn so far are in line with other microbiological active substances evaluated by other MS and peer reviewed within the EFSA process.

Summary of dossiers evaluated IVC

- 5 -

6. Evidence of recognition and acceptance by EFSA, ECHA, EU, Member States.

The reflections of the Ctgb on the comments of Co-RMS, other MS and EFSA appear well founded, scientifically sound and clear.

The conclusion of classifying B. as a low risk substance is in line with other microbiological plant protection products with similar properties and uses.

7. Level of adequateness of the response to comments, questions and suggestions from Member States' expert.

During the peer review process, the comments received from the Notifier, EFSA and other MS were responded to adequately and the answers given were clearly formulated. The process appears transparent and clear.

8. Other criteria.

No inter-zonal product evaluations are yet available due to the non-finalised active substance evaluation process.

9. OVERALL STATEMENT B. MICROBIOLOGICAL PEST AGENT

The dRAR of the microbiological active substance (pest control agent) B. is well prepared, transparent and the areas of concern are clearly indicated so far. The process is still ongoing, pending the further studies required at the peer review.

Also the zonal evaluations of representative formulations are pending and thus the final conclusion of the scientific process in the Ctgb concerning this active substance cannot be drawn.

However, the current phase is easily traceable due to well-organised files in the DMS of the Ctgb, and thus no specific concerns were found concerning the quality of the risk assessment.

There is evidence of internal peer review of the dRAR within the Ctgb and discussion by the Board.

C. Active substance

Draft Renewal Assessment Report under peer-review – Plant Protection Product

Fungicide, NL is the current RMS, dRAR was presented for public consultation on EFSA website. Most documentation and correspondence on C. from the Ctgb website concerns the assessment of products containing C. as well as other active substances.

Criteria and comments

1. Confirmation of compliance with legislation and guidance documents

The assessments of C.-containing products appear to be compliant and accurate.

The dRAR presented to the EFSA public consultation appears to be compliant and accurate.

2. Clarity and comprehensibility of the Scientific Opinion

Information on the assessment of products is clear and understandable.

It is less understandable why the Ctgb has outsourced to a contract laboratory working for industry, the assessment of equivalence among products by different producers. The claimed reason is "lack of manpower"

Information presented in the dRAR is clear and understandable

3. Weight of evidence considerations

As far as the products are concerned, and with the above caveat, evidence appears to be accurately considered and weighed.

The active substance presents possible concerns for developmental toxicity and ecotoxicity in vertebrates; the relevant evidence appears to be accurately considered and weighed in the dRAR.

4. Evidence of collegiate feedback and/or peer reviews

An issue concerning timing: the assessment of equivalence (C. submitted by several Applicants) was externalized and this caused a delay, that was flagged by the Applicant concerned.

It remains the open question about the reasons why to externalize such a basic evaluation as equivalence.

Whereas the problem concerning the delayed time schedule was eventually solved, the externalization did not work very efficiently, in this case, since it produced a delay (justification provided to the applicant: deadline for providing evaluation was misunderstood).

Summary of dossiers evaluated IVC

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5. Level of consistency and coherence

The assessments of C.-based products appear to be straightforward and in line with other similar assessments.

The dRAR going to peer-review is consistent and coherent with other dRARs/DARs

6. Evidence of recognition by EFSA, ECHA, EU Member States

The dRAR is still under peer-review.

7. Level of adequateness of the response to comments, questions and suggestions from Member States' experts

See above.

8. Other criteria

The IVC questioned Ctgb why such a basic evaluation as assessment of equivalence among different was externalized and the answer raised some concern:

The assessment was externalized because the manpower of Ctgb is insufficient.

The externalization was carried out by a consultant based on an agreement between Ctgb and the consultant. The IVC notes that the consultant is a contract laboratory - albeit a reputable one - working for the industry. Issues of confidentiality may arise.

Indeed, the externalization did not work very efficiently, in this case, since it produced a delay in the regulatory process.

9. OVERALL STATEMENT C. ACTIVE SUBSTANCE

The dRAR for C. re-evaluation was presented for public consultation on the EFSA website. The active substance presents possible concerns for developmental toxicity and ecotoxicity in vertebrates; the relevant evidence appears to be accurately considered and weighed, in compliance with up-to-date guidances.

Most documentation and correspondence on C. that I was able to retrieve from the Ctgb website concerns the assessment products containing C. as well as other active substances: the product evaluation was well-documented, clearly presented and sound. A minor issue of delay arising from the externalization was noted. This issue pointed out a problem of externalization due to lack of manpower. Moreover, there is an agreement for externalization to a contract laboratory closely related to industry which raises issues of perceived confidentiality.

D. Active substance

Draft Renewal Assessment Report (dRAR)

Fungicide, renewal application Rapporteur Member State (RMS): NL, Co-Rapporteur Member State (CoRMS): BE

Criteria and comments

1. Confirmation of compliance with legislation and guidance documents

The RMS received the dossier presented by several companies and checked the completeness, the admissibility was communicated to EFSA and the EU Commission according to the Regulation and guidance documents.

Pre-submission meetings are properly recording in the DMS system, as well as Co RMS comments on the draft RAR.

The initial dRAR was sent to EFSA, and according to the Regulation was also distributed to MS. After the consideration of comments, it was concluded that an expert consultation was needed for areas of mammalian toxicology, residues, environmental fate and behavior and ecotoxicology.

The latest version of the dRAR was prepared by NL and included results of expert consultation in some areas as well as the result of Commenting RMS after the PPP Expert meeting. At this point there is a critical concern considering the results of the carcinogenicity studies and the subsequent classification of the substance.

Critical areas of concern were identified including the high risk to amphibians and to fish in all proposed uses, the relevance of metabolites and ground water metabolites due to the classification, and genotoxicity of residues for consumers.

There were several data gaps addressed in the areas of identity, physical /chemical properties, analytical methods, residues, environment fate and behavior.

The EFSA's Conclusion on the peer review is available, as a sanitized version due to the pending studies on classification of the substance.

At the moment the classification of the substance has been sent for comments.

2. Clarity and comprehensibility of the Scientific Opinion.

The areas of concern and data gaps were identify in the dossier and different criteria concerning some critical issues was clearly marked in the latest version of the dRAR, including conclusions reached at the Peer review meeting.

3. Weight of evidence considerations.

Considering the critical concern on classification of the substance according to carcinogenicity, the RMS considered and maintains the opinion that a lower category should

be sufficient (in agreement with current harmonized classification) due to quantitative differences in metabolic fate between rodents and humans.

However, the peer review experts noted that no specific data on D. are available to demonstrate these quantitative differences, so they maintain the more conservative approach.

Such an important disagreement should be discussed internally within the Human Toxicology team but there was no record of these discussions in the DMS system. That would have been useful for the IVC evaluation and for the training of new members of the Team.

4. Evidence of collegiate feedback and/or peer reviews

All the comments of Co-RMS, EFSA, MS are properly recorded in the DMS system and clearly documented and classified, although there are some empty folders, it was possible to trace back most of the information.

5. Level of consistency and coherence

The dRAR is not finished yet due to the pending evaluation from Harmonized Classification and Labelling (CLH) on the classification of the substance. The complexity of the dossier and the significant amount of issues found in critical areas makes it difficult to evaluate consistency and coherence.

6. Evidence of recognition and acceptance by EFSA, ECHA, EU member states.

There were some comments on the presentation of scientific information in the initial dRAR presented to EFSA, concerning tables with the results of studies that were amended by Ctgb in later versions.

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

All the responses to comments, questions and suggestions were recorded and addressed adequately by Ctgb and answers were given to MS.

7. OVERALL STATEMENT D. ACTIVE SUBSTANCE

The latest version of the dRAR is clear in terms of the identification of critical areas of concern and the different views of the RMS, and all conclusions of peer review were properly recorded.

In assessing the scientific quality of the report, it would have been advisable to have more information on the internal discussions within the Ctgb (Human Toxicology Team), in particular with regard to the classification of the substance in terms of its carcinogenic effects and the scientific reasons for the position maintained by NL as RMS Member State.

The final conclusion on the renewal of the substance is pending on the Harmonized Classification and Labelling CLH.

E. Active substance

Draft Assessment Report – Plant Protection Product

Herbicide. NL acted as the RMS (ES was co-RMS). Peer-Review of dRAR.

Criteria and comments

1. Confirmation of compliance with legislation and guidance documents available

dRAR submitted by NL to EFSA.

EFSA distributed the dRAR for comments, and conducted a public consultation. EFSA collated and forwarded all comments received to the European Commission.

During the peer review several data gaps were identified: in particular concerning the environmental part.

The re-evaluation prepared by NL was accepted as regards the assessment of risks for human health.

However, concerning the Environmental part, the peer-review evidenced several disagreements on the interpretation of EU regulations/guidances between the RMS on one side and EFSA/other MS on the other side.

Some disagreements were potentially relevant to conclusions: degradation in soil, degradation in aquatic environment, assessment of mesocosm effects, identification of potentially bioaccumulating metabolites in fishes,

Overall these disagreements concerned the characteristics related to persistence, i.e., a main issue for the evaluation of the active substance

2. Clarity and comprehensibility of the Scientific Opinion

The overall presentation of available data and their use is clear, complete and understandable

A number of data gaps and areas of concern were identified, highlighted with clarity and using science-based argument

3. Weight of evidence considerations

E. is clearly a compound presenting concerns, from both the standpoints of human health (developmental toxicity, endocrine activity) and potential environmental persistence. Concerns were well identified and weighed

Some data gaps were not agreed by the RMS, namely, on the specification for toxicologically relevant nitroso-impurities and on the need to identify two potentially bioaccumulating metabolites.

Summary of dossiers evaluated IVC

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An additional data gap was the lack of availability of some relevant studies from the systematic literature search, despite the request by the RMS.

4. Evidence of collegiate feedback and/or peer reviews.

Significant requests for additional data originated as a conclusion of the EFSA peer review.

All correspondence is clearly documented and includes the remarks/disagreement of EFSA and other MS with the dRAR-led feed-back and discussion within the Ctgb teams.

In particular, feed-back concerning the different interpretation of guidance and criteria for assessing environmental persistence were discussed within the ENV team.

5. Level of consistency and coherence of the dRAR/CAR

Besides the points of disagreements noted above, the assessment of E. is accurate, straightforward and in line with other dRARs and CARs.

6. Evidence of recognition and acceptance by EFSA, ECHA, EU member states.

Besides the points of disagreements noted above, the dRAR of such a substance, presenting several concerns, was well accepted by EFSA and other MS.

Even when not accepted, the reflections of the Ctgb were sound and helped the elaboration of the assessment.

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

During the peer review process, the comments received were responded to adequately and the answers given were clearly formulated.

7. OVERALL STATEMENT E. ACTIVE SUBSTANCE

Ctgb carried out an accurate and sound assessment on a substance presenting a number of issues (mammalian toxicity as well as to the environment) and data gaps, as well as raising many comments from EFSA and MS.

On some relevant issues the final conclusions of the peer-review were not in agreement with the RMS, which is actually understandable.

The different conclusions reached in peer-reviewing were fed-back and discussed within the Ctgb, in particular by the ENV team concerning criteria for assessing environmental persistence.

Comments on selected Products Dossiers

F. Biocidal Product

There are many Biocide products containing A. which have been notified in batches of related products by different applicants. Ready-to-use baits were originally formulated with a higher content of active substance but a later application for major change was made and concentration was subsequently lowered. Seven examples of formulations were evaluated.

F1. NL was (mutual recognition) MRS

F2. NL was zonal (rapporteur) RMS

F3. NL was (mutual recognition) MRS

F4. NL was (mutual recognition) MRS

F5. NL was (commenting) CMS

F6. Application for major change (reduction in concentration of active in ready-to-use bait). UK was (rapporteur) RMS which concluded that conditions under the EU Biocides Regulation 528/2012 (EUBPR) were fulfilled and NL as (commenting) CMS agreed.

F7. IE was (rapporteur) RMS, NL was (commenting) CMS.

Criteria and comments

1. Confirmation of compliance with legislation and guidance documents.

The assessment documents produced by or contributed to by NL seem to be in compliance with the relevant and adopted EU guidances and the biocides legislation

2. Clarity and comprehensibility of the Scientific Opinion

Clarity and comprehensibility of the Assessment Reports are high. Additional data are evaluated logically and the conclusions reached are clear. Considered views are contributed to the between-MS evaluation of zonal data and documented exchanges.

3. Weight of evidence considerations.

In general conclusions are clearly based on the data and the supporting documentation provided.

4. Evidence of collegiate feedback and/or peer reviews

Difficult to assess since most documents except Assessment Reports are solely in the Dutch language. Where exchanges of comments are in English they show clear and well-argued reasoning. Not all comments have been accepted by the relevant RMS. Robust comments

from IE as RMS defended the use of more conservative considerations than were made in the renewal CAR (NL was RMS).

5. Level of consistency and coherence

The documents examined seem to be consistent in their approaches, content and presentation

6. Evidence of recognition and acceptance by ECHA, and EU Member States

Clearly the principal documents have been accepted by ECHA and the involved MS.

7. Level of adequateness of the response to comments, questions and suggestions from Member States' experts

Documented comments from other MS appear to have been considered, some accepted and some not according to clear scientific arguments.

8. Other criteria

It proved very difficult to follow the trail of some of the actions and to locate the documented involvement of the Board. One set of products were listed as going to a particular Board meeting, but were not listed amongst either the papers or the agenda of that meeting (they went to the following Board meeting). The majority of links to Board considerations were only discovered by the systematic examination of the large number of papers listed and considered at each Board meeting through a 3_year period. This information was found in the Board dossiers but is not recorded in the summary spread sheet of action dates for the biocide products (Report product authorisations).

Only the Assessment Reports were dual language (Dutch and English). Most other relevant documents appear to be only in Dutch, including the conclusions of the Board's Authorisation decisions (which are not translated into English).

9. OVERALL STATEMENT F. BIOCIDAL PRODUCT

The overall impression was that the different roles of Ctgb as (rapporteur) RMS, (commenting) CMS and (mutual recognition) MRS were conducted effectively, clearly and, as far as could be understood, with scientific balance and in general, good documentation.

G. Biological Plant Protection Product

Biological fungicide for the control of various soil and seed-borne diseases in horticultural and agricultural crops, outdoor and greenhouse uses.

Extension of the renewal of authorisation based on inter-zonal core evaluation prepared by DK for the Central and Northern zones of the EU.

Criteria and comments

1. Confirmation of compliance of the Decision with adopted guidance and/or legislation

Application -> Ctgb extension of authorization decision, based on the extension of the active substance approval.

Notification for intended zonal applications.

Intended uses are identical to the core assessment prepared by BE, also risk mitigation is identical.

Soil drench application is the worst case for national assessment -> soil non-target arthropods.

No toxins, low risk.

Apparently the inter-zonal evaluation of this product is ongoing and no conclusions available yet.

Pollinator data was submitted recently.

The national RA and the Board decision appears to follow the EU legislation on mutual recognition and data requirements for microbial pest control agents laid down in the Commission Regulation 284/2013 for plant protection products.

2. Clarity and comprehensibility of the Decision

It was not quite clear, why in the DMS folder of this product there are recently uploaded documents on other biological products containing other microbial pest control agents (obviously for the purpose of comparison, however not explicitly mentioned)?

The documentation is easily available in the DMS of the Ctgb.

3. Weight of evidence considerations.

No national evaluation available yet

4. Evidence of collegiate feedback and/or peer reviews of draft Decisions

No documented evidence of internal peer review available yet.

5. Level of adequateness of the response to comments, questions and suggestions of the Board

The documentation in the Ctgb DMS was not very easy to follow, including documents concerning some other products and active substances in this folder?

The correspondence with the Applicant is well documented in the DMS and easy to follow.

6. OVERALL STATEMENT G. BIOLOGICAL PLANT PROTECTION PRODUCT

The current decision of the Board is well justified and supported by data and communicated with the Applicant. The NL National Addendum is under preparation, and no drafts were available, so it is not possible to draw final conclusions at the moment. The overall risk assessment and decision process is easily traceable and transparent so far. The decision is in line with the EFSA conclusions of this low risk MPCA active substance.

H. Biological Plant Protection Product

Biological insecticide in greenhouse cultivations.

The MPCA is a fungus naturally present in the environment.

National authorisation of the PPP based on the inter-zonal core evaluation prepared by the NL. BE will prepare the zonal re-evaluation

Low risk product.

Criteria and Comments

1. Confirmation of compliance of the Decision with adopted guidance and/or legislation

Ctgb decision on the extension of the authorization.

The national assessment prepared by the Ctgb is well prepared, clearly argued for waiving certain data. Significant number of new studies not evaluated before were submitted to support the formulation risk assessment.

Main issues: New studies since the EU risk assessment.

2. Clarity and comprehensibility of the Decision

The documentation is easily available in the DMS of the Ctgb.

National assessment for the NL is well prepared, clear argumentation on waiving certain data on this low risk active substance.

The national RA and the Board decision appears to follow the EU legislation on mutual recognition and data requirements for microbial pest control agents laid down in the Commission Regulation 284/2013 for plant protection products.

3. Weight of evidence considerations.

The argumentation for waiving certain data is well justified and the discussion between the risk assessors and the Applicant is excellently documented.

4. Evidence of collegiate feedback and/or peer reviews of draft Decisions

No documented evidence of internal peer review. It might have been expected some peer review, because there was a significant number of new studies to be evaluated for the first time since the EU evaluation of the active substance.

5. Level of adequateness of the response to comments, questions and suggestions of the Board

The correspondence with the Applicant concerning the waiving issues etc. was well documented in the DMS.

The evaluation and decision process was well traceable in the DMS.

6. OVERALL STATEMENT H. BIOLOGICAL PLANT PROTECTION PRODUCT

The overall process of risk assessment and decision is well traceable and transparent in the DMS. The current decision of the Board is well justified and supported by data and communicated with the Applicant during the application process. The NL National Addendum is well prepared and includes a significant amount of formulation data not evaluated before. The decision is in line with the EFSA conclusions of this low risk MPCA active substance. However, no evidence of internal peer review of the risk assessment of this product is recorded in the DMS, although there was a significant amount of new studies since the first EU evaluation of this MPCA active substance.

I. Biological Plant Protection Product

Biological fungicide for post-harvest uses.

The Microbial Pest Control Agent (MPCA) is a fungus naturally present in the environment all over the world.

Mutual recognition decision based on the inter-zonal core evaluation prepared by the UK, new active substance in the NL.

Criteria and comments

1. Confirmation of compliance of the Decision with adopted guidance and/or legislation

Application, Ctgb authorization decision.

The post-harvest use is identical within the whole EU, so the national assessment was mainly covered by the core assessment and the risk assessment is very briefly covered in the decision. Consumer exposure assessed in the core assessment by the UK, not elaborated further by the Ctgb.

NL addendum on efficacy: Efficacy testing referred in more detail, the core assessment is justified for the NL conditions. Environmental exposure and ecotox negligible. Low risk concluded.

Main issues: Classification and labelling: may cause allergy, precautionary statements are well justified to protect the operators.

2. Clarity and comprehensibility of the Decision

The documentation is easily available in the DMS of the Ctgb.

National assessment for the NL is brief but well prepared.

The national RA and the decision appears to follow the EU legislation on mutual recognition and data requirements for microbial pest control agents laid down in the Commission Regulation 284/2013 for plant protection products.

The final decision was made after a hearing period because this is a new active substance in the NL. No evidence of specific issues arose during the hearing.

3. Weight of evidence considerations

The evaluation and decision process appears well documented and clear.

Low risk is concluded, efficacy testing is the main issue in the NL addendum. Post-harvest use is identical within the whole EU.

4. Evidence of collegiate feedback and/or peer reviews of draft Decisions

No documented evidence of internal peer review.

The final decision was made after a hearing period because this is a new active substance in the NL. No evidence of specific issues arose during the hearing.

5. Level of adequateness of the response to comments, questions and suggestions of the Board

The correspondence with the Applicant was well documented in the DMS.

The evaluation and decision process was well traceable in the DMS.

6. OVERALL STATEMENT I BIOLOGICAL PLANT PROTECTION PRODUCT

The current decision of the Board is well justified and supported by data and communicated with the Applicant. The NL National Addendum is brief but justified given the identical use within the whole EU as one zone. The decision is in line with the EFSA conclusions of this low risk MPCA active substance. However, no evidence of internal peer review of the risk assessment of this product is recorded in the DMS.

J. Biological Plant Protection Product

Biological insecticide, outdoor uses and in greenhouses

Renewal of authorisation based on mutual recognition of the central zone core evaluation prepared by BE, NL national assessment

Extension of intended uses into forestry with slightly higher concentration compared to the core assessment.

Criteria and comments

1. Confirmation of compliance of the Decision with adopted guidance and/or legislation

Application, latest Ctgb authorization decision.

Intended uses are identical to the core assessment prepared by BE, also risk mitigation is identical.

Forestry use required a more detailed assessment in the national addendum.

National assessment covers e-fate (persistence & multiplication in soil, PEC_{sw} and PEC_{gw}), ecotox (impact on non-target organisms), efficacy parts of the risk assessment + classification and labelling.

CLP: precautionary statements are well justified to protect the workers for eye irritating properties of the product (caused by other ingredients than the active).

The national RA and the decision appears to follow the EU legislation on mutual recognition and data requirements for microbial pest control agents laid down in the Commission Regulation 284/2013 for plant protection products.

2. Clarity and comprehensibility of the Decision especially in terms of data available, data utilized

The NL national assessment contains the relevant parts of the risk assessment and covers the slightly higher application rate compared to the core zonal assessment prepared by BE.

Summary of dossiers evaluated IVC

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The decision and the risk assessment are well prepared, clear and the documentation is easily available in the DMS of the Ctgb.

3. Weight of evidence considerations.

Precautionary statements and adequate risk mitigation is included in the decision to protect the users and non-target organisms.

4. Evidence of collegiate feedback and/or peer reviews of draft Decisions

No documented evidence of internal peer review.

5. Level of adequateness of the response to comments, questions and suggestions of the Board

The continuum of the documentation in the Ctgb DMS was not quite easy to follow, including documents concerning some other products and active substances in this folder, obviously for the purpose of comparison (however not explicitly mentioned)?

The correspondence with the Applicant is well documented in the DMS and easy to follow.

6. Other criteria

(Note: in addition to this product, there are several other microbial PPPs containing the same organism with other subspecies and strains, with other product names and different uses. Not all of those product evaluations have been scrutinized by the IVC.)

7. OVERALL STATEMENT J. BIOLOGICAL PLANT PROTECTION PRODUCT

The decision of the Board on the authorisation is well justified and adequately supported by data and communicated with the Applicant during the application process. The NL National Addendum to the core assessment prepared by BE appears well prepared and transparent. The risk mitigation measures set on the basis of risk assessment are well justified as a condition of authorisation. The overall process of risk assessment and decision is easily traceable. However, no evidence of internal peer review of the risk assessment of this product is recorded in the DMS.

K. Biological Plant Protection Product

Biological insecticide in greenhouses.

Mutual recognition based on DK core evaluation, NL national assessment

Criteria and comments

1. Confirmation of compliance of the Decision with adopted guidance and/or legislation

Application -> Ctgb authorization decision.

National assessment covers environmental fate (persistence & multiplication in soil, PECsw and PECgw) and ecotoxicology (aquatic) parts of the risk assessment + classification and labelling.

Risk mitigation for NL conditions: ornamental crops, professional users, resistance management.

The national Risk Assessment and the decision appears to follow the EU legislation on mutual recognition and data requirements for microbial pest control agents laid down in the Commission Regulation 284/2013 for plant protection products.

2. Clarity and comprehensibility of the Decision

The NL national assessment is brief but contains the relevant parts of the risk assessment, given that this is a low risk product with no specific areas of concern.

The decision and the risk assessment are well prepared, clear and the documentation is easily available in the DMS of the Ctgb.

The final decision was made after a hearing period because this is a new active substance in the NL. No evidence of specific issues arose during the hearing.

3. Weight of evidence considerations

Precautionary risk mitigation to avoid environmental contamination and to protect non-target arthropods and pollinators in greenhouses is considered in the decision.

4. Evidence of collegiate feedback and/or peer reviews of draft Decision.

No documented evidence of internal peer review.

5. Level of adequateness of the response to comments, questions and suggestions of the Board

The correspondence with the Applicant is well documented in the DMS and easy to follow.

The final decision was made after a hearing period because this is a new active substance in the NL. No evidence of specific issues arose during the hearing.

6. Other criteria

(Note: in addition to this product, there are several other microbial PPPs containing the same organism with other subspecies and strains, with other product names and different uses. Not all of those product evaluations have been scrutinized by the IVC)

Summary of dossiers evaluated IVC

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7. OVERALL STATEMENT K. PLANT PROTECTION PRODUCT

The National Addendum to the core assessment prepared by the DK appears well prepared and adequate for the purpose of mutual recognition, given that this is a low risk microbial pest control agent with a limited use in greenhouse.

Precautionary risk mitigation to avoid environmental contamination and to protect non-target arthropods and pollinators in greenhouses is considered in the decision.

The decision is well prepared, communicated with the Applicant and the overall process is well documented in the Ctgb DMS. However, there is no evidence of internal peer review of the risk assessment of this product.

Court cases

Further details of current Court cases involving access to information

- Currently the main case for Ctgb, concerning access to information, is 'Bijen I' in which De Bijenstichting (an NGO) has requested access to 86 studies which have been submitted to support the authorisation of a number of PPP's based on neonicotinoids. This is the longest court case to date, started in 2011 and still continues. Ctgb is drafting a new decision based on the court verdict. A detailed response describing the Ctgb's approach during this ongoing case has been provided. Indeed, the response may have also a more general value of illustrating the Ctgb position on the challenging balance between the right to confidentiality and the right to transparency:
- The points of dispute center around the grounds for refusing access to the requested information and what kind of environmental information is involved. The Ctgb position is to identify the information relevant to emissions in the environment. The Ctgb currently awaits the Court's verdict about the legitimacy of the specific set of exceptions for commercially or industrially confidential information .
- In order to define what information is relevant to emissions into the environment, the Dutch appeal court (CBB) has asked preliminary questions to the Court of Justice of the European Union (*Judgment of the Court (Fifth Chamber) of 23 November 2016 Bayer CropScience SA-NV and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden Request for a preliminary ruling from the College van Beroep voor het Bedrijfsleven Reference for a preliminary ruling — Environment — Aarhus Convention — Directive 2003/4/CE — Article 4(2) — Public access to information — Concept of 'information relating to emissions into the environment' — Directive 91/414/EEC — Directive 98/8/EC — Regulation (EC) No 1107/2009 — Placing of plant protection products and biocides on the market — Confidentiality — Protection of industrial and commercial interests C-244/14*). Based on the ruling of the ECJ, the Ctgb has devised 'rules of thumb' concerning access to environmental information, which have been presented in its response to the C-244/14 ruling to the parties in appeal and to the CBB

- The regulations concerning access to environmental information are derived from the Aarhus convention. For Member States Aarhus is implemented in Directive 2003/4/EC which has to be implemented in national law. This differs between EU Member States and there is still no EU-wide Guidance concerning this Directive.
- As a result of the answers given by the Court of Justice of the European Union to the preliminary questions in C-244/14, the European Union has started a working group in order to draw up guidance concerning access to environmental information and to harmonise the way in which Member States handle such requests. This working group has been put on hold because the European Commission is still awaiting the verdict of the European courts concerning their access to information cases (eg. C-673/13 P "*Opinion of Advocate General Kokott delivered on 7 April 2016 European Commission Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe)*") based on Regulation 1049/2001 (*Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents*).

The IVC notes that, depending on the outcome, 10 other requests for access to environmental information are on hold while the Ctgb awaits the final verdict on the 'Bijen I' case,. In addition, the CBb has put two similar appeal cases ('Bijen II' and 'Bijen III'), concerning the authorisation of the PPP's based on neonicotinoids for which access to the underlying studies has been requested, on hold as well.

Colofon

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