Report of the third 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

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09/2023

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Executive Summary

An international group of independent scientists was assembled at the request of the management Board to evaluate the performance of the Netherlands Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) during the period 2018 to 2023, as the national competent authority for regulating plant protection products and biocidal products. Ctgb is an independent authority (abbreviated ZBO in Dutch; Zelfstandig Bestuurs-orgaan) which assesses the risks of products and active substances and takes decisions within the European frameworks of the Plant Protection Products Regulation (EC 1107/2009) and the Biocidal Products Regulation (EC 528/2012).

The International Visitation Committee (IVC2023) was tasked with examining the overall scientific and technical quality of the risk assessment outputs, the legal compliance of the evaluations of the chemical dossiers in relation to guidance documents, the scientific quality of the regulatory decisions of the Board of Ctgb, the authorisation of 'green products', regulatory compliance and harmonisation with EU Member States, and wider outreach and its role in the international regulatory community.

During its work, the IVC2023 was granted essential and unlimited access to Ctgb's confidential archives and examined a large amount of written documentation. In addition a significant number of staff at all levels were interviewed on site. Based on the substantial information gathered, the IVC2023 confirmed that the Ctgb is a high delivering regulatory organisation with a strong scientific core. The scientific work of the Ctgb and its outcomes are of excellent quality and respected within the community of risk assessors and risk managers within the EU Member States and internationally. Ctgb makes a significant contribution to the development and harmonisation of EU and international guidance documents.

In accordance with the EU framework, openness and transparency are key principles in risk communication and in the appropriate exchange of timely information. The Ctgb's commendable internal and external communication policies are both proactive and transparent providing open communication to all interested parties. Ctgb continues to build for the challenges ahead as risk assessment becomes more complex and demanding. The IVC identified 15 recommendations to help the organisation further develop its capabilities and streamline some of its processes. Overall the IVC concluded that Ctgb is run well as a strong and effective regulatory agency that has significant resources and capacity to respond to the expectations of applicants and both national and European society.

Samenvatting

Op verzoek van het Ctgb, de bevoegde autoriteit in Nederland voor de toelating van gewasbeschermingsmiddelen en biociden, is een internationale groep onafhankelijke wetenschappers samengesteld om het functioneren van de organisatie over de periode 2018 tot en met 2023 te evalueren. Het Ctgb is een zelfstandig bestuursorgaan (ZBO) dat de risico's van producten en werkzame stoffen beoordeelt en besluiten neemt binnen de Europese kaders van de Gewasbeschermingsmiddelenverordening (EG 1107/2009) en de Biocidenverordening (EG 528/2012).

De Internationale Visitatiecommissie (IVC2023) kreeg de taak om de algehele wetenschappelijke en technische kwaliteit van de risicobeoordelingen te onderzoeken, de wettelijke conformiteit van de evaluaties in relatie tot de richtsnoeren, de wetenschappelijke kwaliteit van de regelgevende besluiten van het college, de beoordeling en toelating van 'groene producten', de naleving van de regelgeving en harmonisatie met de EU-lidstaten, en in een breder kader de rol van het Ctgb in de internationale regelgevende gemeenschap.

Tijdens haar werkzaamheden kreeg de IVC2023 essentiële en onbeperkte toegang tot de vertrouwelijke dossiers van het Ctgb en onderzocht het een grote hoeveelheid schriftelijke documentatie. Daarnaast werd ter plaatse een aanzienlijk aantal medewerkers uit alle geledingen geïnterviewd. Op basis van deze substantiële hoeveelheid informatie, bevestigt de IVC2023 dat het Ctgb een hoog presterende regelgevende autoriteit is met een sterke wetenschappelijke kern. Het wetenschappelijke werk van het Ctgb en de uitkomsten daarvan, zijn van uitstekende kwaliteit en worden gewaardeerd binnen de gemeenschap van risicobeoordelaars en risicomanagers binnen de EU-lidstaten als ook internationaal. Het Ctgb levert een belangrijke bijdrage aan de ontwikkeling en harmonisatie van EU- en internationale guidances/richtsnoeren.

In overeenstemming met het EU-kader zijn openheid en transparantie sleutelbeginselen bij risicocommunicatie en voor een goede en tijdige uitwisseling van informatie. Het interne en externe communicatiebeleid van het Ctgb is zowel proactief als transparant en zorgt voor een open communicatie naar alle geïnteresseerde partijen. Het Ctgb bouwt aan de uitdagingen die voor ons liggen nu de risicobeoordeling complexer en veeleisender wordt.

De IVC heeft vijftien aanbevelingen geformuleerd om de organisatie te helpen haar capaciteiten verder te ontwikkelen en een aantal van haar processen te stroomlijnen. Over het geheel genomen concludeert de IVC dat het Ctgb goed wordt geleid als een sterke en effectieve regelgevende instantie die over aanzienlijke middelen en capaciteit beschikt om te reageren op de verwachtingen van aanvragers als ook de nationale en Europese samenleving.

IVC Report 2023

Introduction

Ctgb

In the Netherlands the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is the competent authority for regulating plant protection products and biocidal products. Ctgb is an independent authority (abbreviated ZBO in Dutch; Zelfstandig Bestuursorgaan) which assesses the risks of products and active substances and takes decisions within the European frameworks of the Plant Protection Products Regulation EC 1107/2009 (EU 2009 a) and the Biocidal Products Regulation EC 528/2012 (EU 2012). Based on the European Regulations, active substances are approved at the Community level while products containing those active substances are authorised at the national level in each Member State. The Ctgb works closely in the EU with the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA) and the competent authorities of the other Member States and its activities are overseen by the Dutch Ministry of Agriculture, Nature and Food Quality (plant protection products) and the Ministry of Infrastructure and Water Management (biocidal products). In topics relating to their particular policy areas, the Ministry of Health, Welfare and Sport and the Ministry of Social Affairs and Employment are also involved.

The Approach

In 2012 and 2017, the Chairman of the Ctgb Board invited separate International Visitation Committees (IVC) of independent European scientists to carry out thorough evaluations of the scientific processes conducted by Ctgb at that time and the scientific quality and legal compliance of those assessments, decisions and other technical outputs of the organisation (IVC 2013 and IVC 2018).

Five years later, in November 2022 the current Chairman of the Ctgb Board, Dr Rob van Lint, invited Dr Tony Hardy to establish the 3rd International Visitation Committee (IVC2023) which was endorsed by the Board to start its work on 1st January 2023 to address the main terms of reference set by the Board (Annex 1):
To evaluate the scientific quality and legal compliance of the decisions on authorisation of plant protection products and biocides. In particular:

Methods

- Quality: the overall scientific and technical quality of the risk assessment documents that are prepared by the secretariat to substantiate the subsequent formal decisions by the Board.
- Process: the (internal) evaluations of submitted dossiers by Ctgb assessors with a focus on the identification of and consistency in dealing with gaps, ambiguities in the assessment framework, data interpretation and conclusions. Also the legal compliance of the process, e.g. is it based on the applicable guidance documents? Compliance with legal deadlines?
- Board: the contribution and role of the Board in the decision- making process, in particular the level of competence and procedural aspects.
- Existing authorisations and possible actualisation with a view to developments in EU legislation (article 56, (EC) No 1107/2009; article 48, (EU) 528/2012)
- Progression in new scientific developments.

To evaluate how well Ctgb deals with demands of all stakeholders (European Commission, ECHA, EFSA, Competent Authorities of other Member States, industry, general public) and apparently contradictory requirements, considering:

- The requirements, procedure and timeframes for product authorisation as set out in the biocides ((EU) 528/2012) and the plant protection products regulation ((EC) No 1107/2009);
- The need for transparency and the existing rules for disclosure;
- 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.
- 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.
- The legal timelines as laid down in the biocides and plant protection products regulations are not met by the Member States. Current practice and theory behind the legal timelines at the time of implementation of the regulations is diverging more and more.

- The role and contribution of Competent Authorities with regard to the European Green Deal, Farm-to-Fork strategy, EU Chemicals Strategy, National strategies, knowing that Competent Authorities are responsible for decisions on the authorisation, while the European and national strategies contribute to a reduction of the use of products.

The Action Plan of the IVC2023 is provided in Annex 5.

The Team

Members of the IVC2023 were identified and selected by the IVC Chair as potential candidates using the following criteria (Autio et al 2021):

- All members should have at least fifteen years of experience in life sciences in the public sector and/or as independent consultants.
- Members should not have any direct or indirect interest in the Organisation or in any of its staff, compatible with the guidelines of European authorities.
- All members should have sufficient knowledge of European Union regulations and other international developments relevant for the task.
- As a group, the committee must have adequate knowledge and experience in the risk assessment and risk management of chemicals in general, and specifically in pesticides.
- All three European Union zones should be represented.

The proposed membership of the IVC2023 was confirmed by the Board of Ctgb and letters of appointment were sent to individuals on 13th December 2022:

- Dr Anthony Hardy, UK, retired civil servant with Department for Environment, Food and Rural Affairs (DEFRA) and former independent expert with the European Food Safety Authority (EFSA) (Chair)
- Dr Sari Autio, Finland, Finnish Safety and Chemicals Agency Tukes
- Dr Alberto Mantovani, Italy, currently retired civil servant, till February 2023 research director at Istituto Superiore di Sanità (ISS)
- Dr Elizabeta Mičović, Slovenija, University of Maribor
- Professor José Tarazona, Spain, Spanish National Environmental Health Centre. Instituto de Salud Carlos III (ISCIII)

Members' CVs are in Annex 2.

Sari Autio was also a member of the IVC2013, and Sari Autio, Tony Hardy and Alberto Mantovani were members of the IVC2018.

Prior to starting work all members of the IVC2023 signed Declarations of Interest in relation to their tasks and Declarations of Confidentiality in relation to the access to and use of confidential information in the regulatory dossiers (see Annexes 3 and 4).

Mode of working

The preliminary meeting of the IVC was held online on 8th February 2023.
Thereafter the Team members regularly held online meetings and exchanged frequent emails throughout the duration of the work programme. The IVC made 3 site visits to Ctgb offices at Ede:

- on 22nd March it met with the Board and Management to discuss amongst other things the Action Plan and the Organisation (Ctgb):
- on 24th and 25th May it met with the Management and the Board and interviewed some 30 staff individually 'or' in their teams. On 26th May the IVC conducted additional interviews with scientific staff, for ad hoc evaluations of the scientific assessment frameworks for PPP and BP in specific dossiers:
- on 27th September it presented its final report to the Board, Management and the staff.

Access to Information: documents

To aid its evaluation work as detailed in the IVC2023's Action Plan (Annex 5), the IVC was given free access to an enormous amount of documented information which included position papers, summaries and descriptions of the entire organisation, including its structure and processes, staff information, internal notes, regulatory dossiers and records of process meetings and follow-up action at all levels. Team members signed confidentiality agreements not to disclose any document or other written reports without the permission of Ctgb. The IVC identified and requested a considerable amount of specific information

from Ctgb (Annex 9) which necessitated access to the vast secure electronic Document Management System at Ede. This also required unrestricted but secure access to the Ctgb intranet. Such requests and access were further complicated by the fact that the current DMS is being transferred to a new IT platform, a task which should be fully completed first quarter of 2024. Members of the IVC experienced many problems to consistently access the Ctgb's IT systems but were particularly grateful for the excellent expert help and support by the technical and scientific staff in overcoming firewall incompatibilities with our remote IT equipment. The IVC was very pleased and grateful to eventually get access to all the information it had requested.

Access to Information: interviews with staff

In order to augment extensive background reading and scrutiny of the scientific process documentation, the IVC visited the Ctgb site over 3 days in May and interviewed some 30 staff individually or in their teams (Annex 10). These included members of the Board, management, scientific risk assessors, project leaders, planners, human resource staff, legal advisors, business operators and communicators. Clarification was sought by the IVC on a wide range of topics including strategic plans, policies for human resources and communication, authorisation decisions, policy advice, project planning and management, scientific risk assessment, team resources, staff development, national and international context.

IVC members had earlier prepared questions which interviewees had not seen. Supplementary interviews were later conducted online including clarification on Ctgb's strategic development plan with Board members and the Executive Secretary/Director.

For the ad hoc interviews on the scientific assessment frameworks, IVC members selected elements from the manuals and guidance documents and questioned individual staff how they had addressed particular issues in their own recent assessments.

Access to Information: follow up to the recommendations of previous IVCs

The report of the second International Visitation Committee (IVC2018), which worked from January – August 2018, contained 11 recommendations addressing the Board, Openness and transparency and the Scientific output and outreach. Ctgb responded in November 2018 and provided a detailed update to the IVC2023 in March 2023 (Annex 7).

The IVC2023 is pleased to see that most points in the 2018 recommendations were accepted by Ctgb and are being addressed. Whilst there are understandable constraints on implementing specific staffing recommendations, the underlying issues have been recognised and considered and are being addressed in Ctgb's strategic plans.

It is strongly evident that Ctgb has improved the constructive and regular interactions between the Board and the secretariat including the scientific assessors. Increased feedback and regular joint topic or theme discussions contribute to the breadth of understanding of the scientific processes and management decisions.

The IVC2023 notes that the central importance of openness and transparency has been fully acknowledged by the Board and improvements made both to the discussions and the archived documentation of international comment and review.

In summary the IVC2023 is very pleased to note the extensive list of developments in the last 5 years. This informative table is reproduced with permission as Annex 8.

Observations and Findings

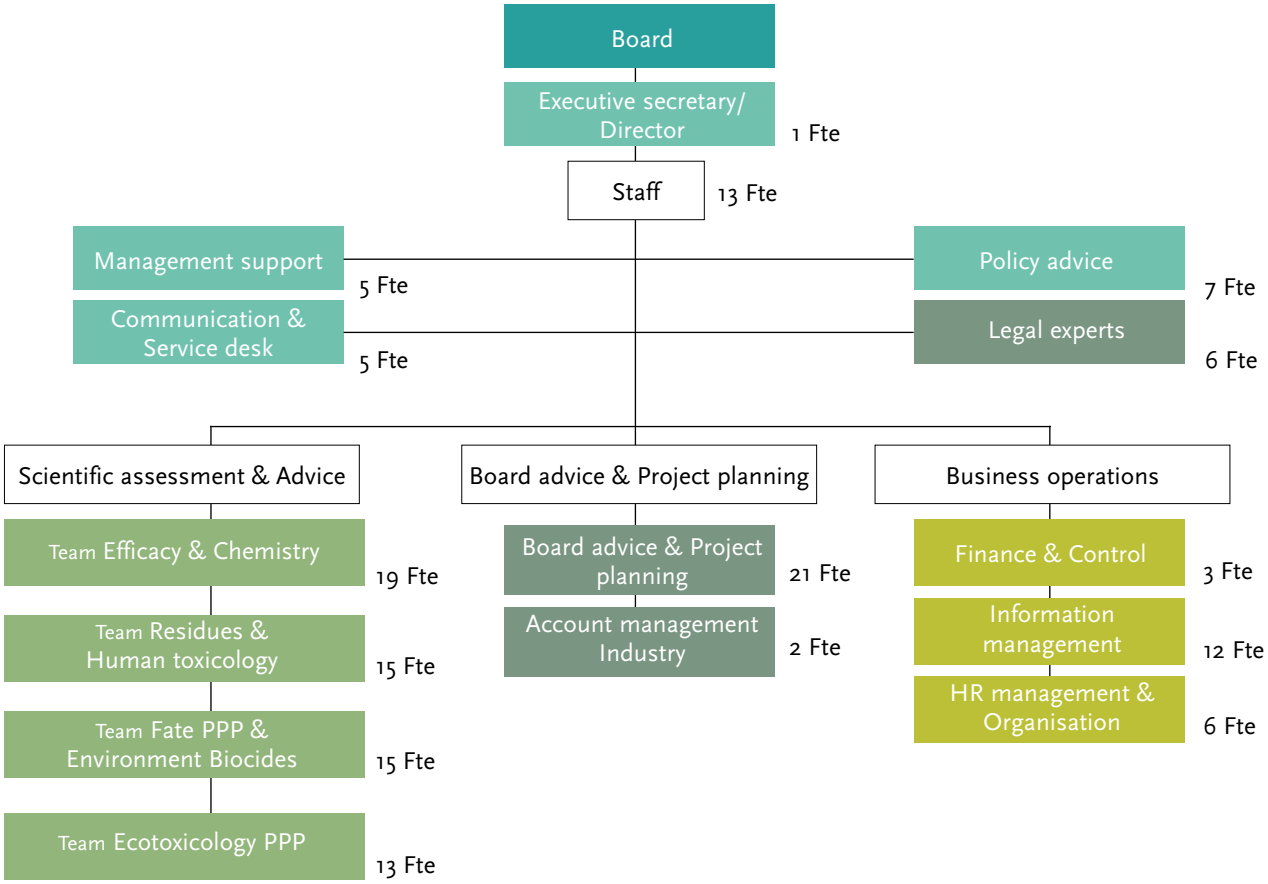
The Organisation

Ctgb structure and management

The current organisation chart of the Ctgb is shown below, Fig.1. The Board which has 9 independent members (Chairman, 4 members and 4 alternate members) is the figurehead of the organisation and is responsible for the authorisation decisions of plant protection products and biocidal products, providing advice to appropriate Ministers, approving the operating plan and budget, the annual report and the annual accounts. They are supported by the Board Secretariat which makes scientific and administrative preparations for the decisions and is led by the Executive Secretary of the Board and Director of the Secretariat.

The scientific assessors for both plant protection products and biocidal products work together in teams within the largest single unit. A huge organisational challenge for Ctgb during the evaluation period was the disruption during the Covid19 pandemic. Staff showed tremendous flexibility and commitment, working mainly from home and digitally. All staff and Ctgb as a whole are to be congratulated for their efforts and new ways of working which resulted in very few delays in the extensive work program (Annual Report 2021 | Annual report | Board for the Authorisation of Plant Protection Products and Biocides (ctgb.nl)). The IVC2023 understands that lessons learnt from this experience will be incorporated into future plans.

Figure 1. Current Organisation chart of Ctgb. At the end of 2022 there were 163 employees (149 fte).



The new organisation of Ctgb

Ctgb is committed to perform high-quality science-based risk assessment and risk management of pesticides and biocides at the EU as well as at the national level. Since its activities are in continuous evolution and development to maintain and improve its performance, Ctgb envisages the periodic need to reevaluate its structure and internal procedures. The recommendations to the Management and Board elaborated by the second International Visitation Committee (2018) contributed to the development of the Ctgb's workplan, for instance, through the increasingly effective and structured cross-talk between the Board, the secretariat and the teams of scientific assessors. Ctgb has also been working on the renewal of its extensive IT application landscape for 2 years and through the implementation of the 'OBSO' (organisation-wide collaboration platform) program is currently migrating its IT to a new secure platform. This will eventually cover all case management (workflow), the document management system (DMS), customer relationship management (CRM), working together in one document, monitoring results and progress and the applicant portal.

The third IVC (January-August 2023) appeared on the scene at a delicate turning point for the Ctgb, just before an important re-organisation involving the teams and ways of working. The new organisation will progressively be introduced from October 2023. Following the decision on the re-organisation, taken by the Director of the Secretariat in December 2022 after discussion with and support given by the Board and positive advice of the Employees Council (in Dutch the 'Ondernemingsraad'), Ctgb will re-organise into two separate departments for plant protection products and biocidal products, with the scientific staff working under matrix management in new, structural multidisciplinary teams.
Whilst the IVC recognizes that this re-organisation is outside its terms of reference, nevertheless, the IVC deemed it useful to consider Ctgb's motivations and aims in order to better understand the future organisation and its responses to current workflow issues. In particular, based on the staff interviews, the IVC considered it highly relevant to get a comprehensive overview of the planned multidisciplinary teams and the expected favourable impact on the scientific quality of the Ctgb's assessments and the working efficiency. Hence, a meeting to discuss this topic took place on July 6 2023 between the IVC2023 team and the Ctgb Board and management.

The Board and management representatives clarified for the IVC that the two main motivations concerned:

(a) efficiency, in particular time-effectiveness, which is a critical issue in view of the current, lengthy assessment process across the whole EU. An additional, significant aspect is how to optimize the use of the "dead times" during the processing of an application which under "stop the clock" procedures may require more data.
(b) improving interdisciplinarity and optimisation of working according to the process flow as the main approach to maintain and strengthen the scientific knowledge development of individual staff.

Thus, the re-organisation pivots around the organisation of multidisciplinary teams that will deal with all aspects of a dossier, facilitating the "ownership" of the assessment by the whole expert group. Team leaders and senior scientific staff will in particular ensure consistency of approaches and decisions across assessments. The IVC noted that whilst this new way of working may represent a challenge, it fully recognises that it also represents an important opportunity for Ctgb.

The management and Board representatives also pointed out to the IVC that the planned re-organisation is intended to meet the increasing expectations about Ctgb from Dutch societal stakeholders and policy makers. Most importantly they affirmed the inclusive approach proposed, through the stepwise involvement of all staff. In particular both of the new Biocides and PPP departments were invited to suggest how to organize their multidisciplinary teams; also, staff members have already been involved in and are kept up to date in weekly sessions of questions and answers.

The IVC noted that the involvement of the staff was apparent in the large majority of interviews. Meanwhile, the IVC pointed out that keeping and maintaining clear and transparent criteria and procedures for selecting candidates for lead and/or senior positions is essential to ensure good functioning, mutual trust and team spirit. This view was fully shared by the Board and management representatives. Overall, the IVC was greatly pleased by the openness and willingness of the Ctgb Board and management to discuss the planned re-organisation. This was very helpful to set the context and to fine tune the IVC's recommendations.

Human Resources

Staff records and recruitment

The IVC team had access to the Curricula Vitae of 119 staff and resumes for 9 Board members. Information has been collected from the CV forms, and from the Ctgb presentation on 24 May (Annex 6). The CV form includes the basic data requested by IVC, such as the current competences in a specific area of work, 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 organisations or companies prior to their appointment to Ctgb, information regarding participation in relevant courses, symposia, congresses, working groups, list of relevant publications, and participation in the work for EFSA, ECHA, and other European and international organisations contributing to procedural or technical harmonisation.

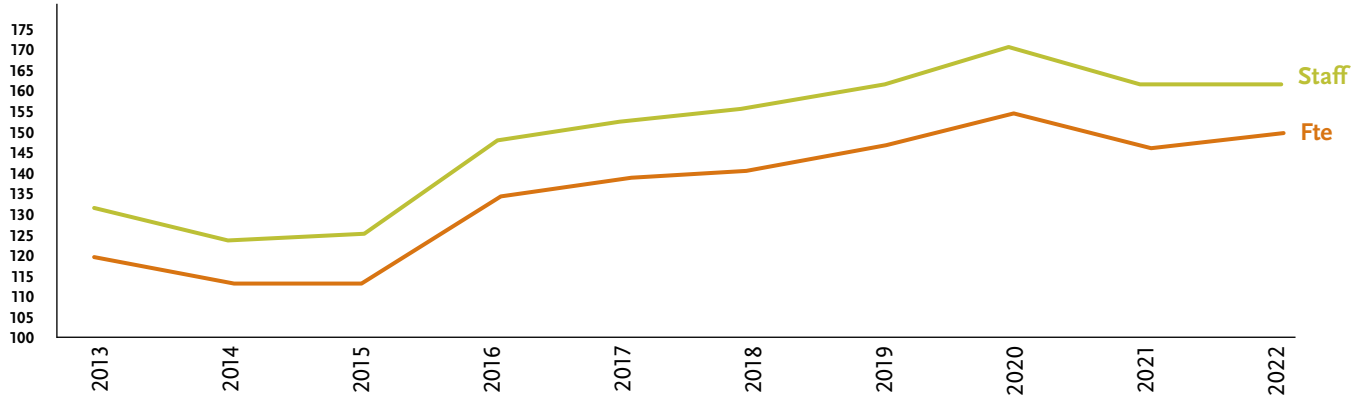
The completeness of responses in the CV's was very diverse. Some of the CV's are very limited and incomplete in their information content, lacking data on participation in relevant courses, symposia, congresses, working groups, or years in relevant areas of work. However, many CV's are complete, with explicit descriptions regarding experience, skills and knowledge.

Based on the appraisal of available information the IVC concludes that the majority of staff involved in scientific risk assessment are highly qualified with specific knowledge, experiences and skills in all necessary areas of work regarding plant protection products and biocides.

It is obvious that multidisciplinary teams with different expert knowledge are available and capable to deal with the complex tasks needed in the risk assessment process. Some staff members are very active in their respective scientific areas, with several active participations in international conferences and with relevant publications. Although deepening scientific knowledge is not considered to be core business in Ctgb's staff policy (since Ctgb is not a research institute), the IVC did consider the number of scientific publications as part of the evaluation of the individual's scientific background and knowledge level. All risk assessment teams have produced an important number of relevant publications, with a significant figure as first author. The numbers of publications per team reflect well the scientific expertise level of each team.
Most importantly, data from the CV's show active participation in the work of EFSA and ECHA as well as other International scientific/regulatory organisations (for example OECD Working Group on Pesticides, JMPR) competent for pesticides/chemicals safety evaluation and/or contributing to procedural or technical harmonisation. Involvement in the development of specific EU PPP and Biocides Guidance Documents is evident and effective.

On 31 December 2017 the number of employees was 154 and on 31 December 2022, it was 163 employees, a gain of plus 6%, Fig 2. Nevertheless, finding and retaining staff remains a challenge for the Ctgb as it has to deal with relatively high turnover of scientific assessors. Opportunities to create new positions and to realize internal growth opportunities have not yet been fully exploited. A step towards this is expected in the re-organisation.

Figure 2. Number of employees between 2013 and 2022: the number of staff (green) and the number of fte (orange).



The IVC also noted that certain risk assessments were outsourced (approximately 2 Fte) because of the lack of internal experts. The IVC considers that outsourcing should remain confined to cases where highly specialized areas of expertise are not available at the Ctgb.

Staff policy, development and training

Throughout the onsite IVC visitation from 24th to 26th May, the contact with all staff at all levels has been very helpful, pleasant and forthcoming. Moreover, the IVC noted this culture of collegiality and that the overall atmosphere was one of confidence. Access granted to the IVC to documents, reports, notes, etc. was unlimited and much appreciated. The IVC was informed by the HR management that as part of the revision of the policy for all staff:

- There is a personal yearly activity plan including the need for or wish to follow a course, to attend a conference, to undertake specific training, etc.
- Newly recruited risk assessors are trained by an allocated mentor, who gives them instructions, advises them and helps in specific situations for at least a year;
- All scientific staff are given approximately 100 workhours each year to be used for their further scientific and/or personal development without accountability conditions.

Since 2018 Ctgb has further increased efforts to motivate staff over personal developments and to create a satisfying and healthy work environment with the aim of retaining employees. During the Covid19 pandemic the Ctgb organised working from home with the aim to keep employees motivated and Ctgb succeeded in this. Based on this positive experience, Ctgb decided that working from home should become regular working practice. A hybrid working program has therefore been set up and it is appreciated by Ctgb employees. Overall, the IVC observed a positive working environment for staff as result of all the commendable efforts Ctgb has put into human resources. On the other hand, the IVC realised that regarding promotion possibilities, there is lack of clear criteria for example when several candidates fulfil all general conditions. In the absence of clear selection parameters, such situations could create unnecessary dissatisfaction, which might even impact adversely on the current highly collaborative atmosphere. In addition, for scientific staff, the internal structure offers limited possibilities for promotion other than by moving to managerial positions. The new organization will provide some new opportunities for seniors, but still at grades lower than those with managerial responsibilities. This situation forces senior scientists looking for further progression of their professional career either to move to managerial positions or to options outside Ctgb. The new matrix organisation may offer Ctgb the possibility to establish a scientific career path, as part of the knowledge hub and expertise management, without team/unit management responsibilities, to further improve the attractiveness of Ctgb to highly experienced regulatory scientists.

Maintaining a highly skilled workforce is of necessity an important goal for Ctgb. The highest level of education is one of the criteria considered relevant to assess the quality of the scientific output of the Ctgb. The IVC can confirm the high level of education, as identified by a master's degree and PhD, among employees. They are well trained, well qualified and reasonably well motivated. The IVC noted that not all eligible staff members are formally recognised as European Registered Toxicologist (ERT), but the number of registrations rose from the previous IVC visit to a significant level. The IVC is also pleased to note that Ctgb is encouraging its ecotoxicology staff to register with IBERA (the International Board for Environmental Risk Assessors) which is funded by SETAC Europe (IBERA 2023).

Alongside the education level, professional experience is considered an important contribution to the quality of the science output. The number of years of relevant experience before and after joining Ctgb are not available in all CV's. It should be noted that there was no information on experience before joining the Ctgb for some experts. As the information provided by the CV's available was often sparse, the IVC was not able to draw firm conclusions. However, some pertinent observations include:

- The majority of scientific assessors participate regularly in training courses relevant to their area of work and co-author scientific publication. Some of them are invited to present lectures in specialised workshops and conferences;
- Risk assessors participate in various European regulatory or scientific working groups mainly in EFSA and ECHA. In particular, Ctgb assessors also

participate in the development of relevant guidance documents at EU as well as OECD level, applicable to the risk assessment of plant protection products or biocides.

Declaration of Interest

Annual declarations of interest and policy are a tool providing insight into trust, transparency and mutual understanding, in order to share openly when a particular interest may be considered 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. During the interviews with the staff, the IVC found that Ctgb does not have trouble or problems with possible conflicts of interest and the implementation of its Doi policy among the personnel. Furthermore, the IVC supports Dutch national 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 two years.

RECOMMENDATIONS

1. **Invest in finding and retaining personnel using different activities: promotional campaigns, news and short TV spots with presentation of Ctgb, promote active attendees of Ctgb staff at symposiums, conferences and other events related to Ctgb's field of work;**

2. **Ctgb should create clear and transparent criteria for use in situations when several candidates fulfil all general conditions for promotion; in addition, Ctgb should explore the option for setting a parallel scientific career path for retaining and attracting senior regulatory scientists;**

3. **Provide a standardised format for CV of personnel (for example the CV Europass which is widely used elsewhere in the EU) and review regularly (annually) that submitted forms contain complete and up-to-date information;**

Openness and Transparency

During the interviews with the Communication team and the Board, the IVC realised that there is a high interest in the work of Ctgb among citizens. It is commendable that all relevant target groups of stakeholders are identified by Ctgb (applicants, users, NGO's, politicians, government organisations, media, experts and the general public).

Communication policy

Ctgb's policy for communication is appropriate, clear and functional in practice and its internal rules for staff regarding communication (both internal and external) are clear, understandable and user friendly. The IVC concluded that all provisions appear to be implemented in practice in a very effective way. The central principles that Ctgb's work is based on are honesty, expert knowledge, transparency and independence, as well as its rules of communication, which include proactively informing stakeholders. Providing all the necessary information in advance, on time, and unambiguously to avoid possible misunderstanding, concern, fear or distrust is an important goal of the organisation. Development of public trust requires clear, effective and open communication with the outside world, which includes all stakeholders both national and the wider international regulatory community. The IVC acknowledges that Ctgb puts a lot of effort into increased transparency throughout the risk assessment and risk management processes and the IVC concludes that the communication policy is implemented in practice to a high standard and with great effect.

External communication

General information about Ctgb is available on the web site and includes all relevant data aimed at recognised target audiences including press, business operators, general public and experts. All relevant information is readily accessible and user friendly. This includes Ctgb's clear and transparent Annual Reports (https://english.ctgb.nl/documents/annual-reports/2023/04/18/annual-report-2022).

Questions about plant protection products, biocides, Ctgb methodology, authorisations, assessment frameworks,

application procedures and the authorisations database can be sent to the Service desk by the general public, users of plant protection products or biocides, distributors and industry. This unit provides all the necessary support to business operators, as well as pre-application support to applicants, freely available every day with clear and simple instructions. There are up to date news releases and newsletters, which include all important, interesting news and upcoming events regarding Ctgb's work and responsibility. On the Ctgb web site there is also general information on various subjects regarding the work and tasks of the Organisation.

The IVC assesses the splitting of the external communication between the Service desk and the communication unit to be very effective and positive. The communication team is responsible for preparing answers for the media, representatives of non-governmental organisations (NGO's), the general public and answers on policy-relevant, sensitive questions. It works very professionally at a high level, taking full account of all written communication rules in practice. Written answers are prepared in very short time (in a maximum of 3 days), which is excellent and shows a high level of responsiveness and very good organisation. Statements on TV in front of camera are strictly the responsibility of the director and chairman of the Board, who are properly trained in communication skills and well informed about important issues. The IVC noted Ctgb's recognition of risk perception by the public regarding chemical hazards, e.g. worries, fear, doubts and distrust. Having identified all target audiences, the Ctgb uses different communication tools (social media, web site, Facebook, Instagram, Twitter (X), media, press releases, press conferences etc) to reach specific stakeholders. Ctgb recognises the diversity of groups within the public such as supporters, doubters and opponents, which require different ways of communication, key messages and the choice of words. It is commendable, that many different infographics and other images are used to communicate more complex and science-based information. Meanwhile, the IVC notes that there is still space for additional promotional events, thus creating more possibilities to present the work and vision of the Ctgb to the wider public.

During onsite interviews with staff, the IVC recognised that the main challenges for Ctgb remain communication with NGOs, dealing with mis-information and the gap between expert view and average consumer's views. However, the IVC recognises that Ctgb is fully aware of these issues, hence, IVC encourages Ctgb to maintain the current efforts to strengthen proactive communication.

RECOMMENDATIONS

4. **Preparing communication plans for promotional events in advance will be beneficial and could achieve a higher level of transparency and increase public trust.**

5. **Organising additional joint events, and inviting the different interested target groups to present and explain their specific topic, would give a targeted opportunity to provide answers on difficult questions.**

Internal communication

Besides effective external communication, Ctgb also puts a significant effort into internal communication. There are news items for staff, agenda and calendar for important and interesting events available on the intranet, as well as all necessary and commonly-used forms for all employees (maternity leave, participation in seminars, training courses, new vacancies at work). Ctgb provides a regular programme of open coffee meetings with the possibility for any employee to suggest topics for discussion. Information about new possible positions and new jobs opportunities at Ctgb are transparent and available for all interested staff. Providing two basic sorts of information: "need to know" and "nice to know" functions very well and ensures a high level of satisfaction among staff. Additionally, Ctgb creates different possibilities and organises events for internal communication between different sectors, between management and the Board. The IVC noted that all employees have access to important information. The staff are also motivated to actively suggest proposals to improve and optimise work processes. Overall, creating a pleasant and open working environment is very important for Ctgb. During the interviews, the majority of staff expressed a high level of satisfaction with working in this agency.

However, it is apparent from the interviews that there are still some unhappy, concerned and worried staff. They highlighted the lack of communication among different teams and between teams and the Board, mainly

regarding the upcoming re-organisation. Therefore, the process of informing and involving staff might need further improvement and the IVC notes that management is addressing this issue.

RECOMMENDATIONS

6. **The management should put additional effort into encouraging all possibilities for internal communication between different teams and with the management and the Board, especially regarding future reorganisation.**

7. **The management should give all employees the opportunity to seek and receive information and answers about reorganisation. In addition, the management should encourage staff to express their own opinions and suggestions.**

Legal support, legal mandates, issues, compliance

The Dutch decree on the Mandate, Authorisation and representation by the Ctgb (NL 2018) was updated just after the previous IVC 2018 had finalized its report. The members of the current IVC fully appreciate that the Ctgb satisfactorily complies with the requirements of relevant EU and national legislation wherever possible in its work, although the NL, similarly to all Member States, at times struggles to meet the EU legal timelines. The Ctgb provides the ministerial representatives of the NL with high quality practical support in their active participation in the development of EU and international legislation within the field of plant protection products and biocides.

Although it was not possible to review all the Guidance Documents used by the Ctgb, the IVC concluded on the basis of a comprehensive evaluation of the manuals and assessment frameworks for PPPs and Biocides, ad hoc spot checks and selected decisions, that the key guidance for plant protection products and biocides is adequate and up to date for conducting high quality evaluations and making decisions on those substances (see additional details at the scientific assessment section of this report, page no.23). The members of the IVC fully appreciate the contribution of Ctgb staff members to the development of EU Guidance Documents.

The legal team of the Ctgb consists of five colleagues with the main task of providing legal support to the decision making of the Board and management of the Ctgb as well as to the scientific risk assessors. The most typical issues where support is required from the legal team are interpretations of specific articles of the regulations and confidentiality/data protection issues. The risk assessors are facing the issues of comparative assessment and possible substitution of the most hazardous pesticides (Candidates for Substitution, CfS). This is where support in interpretation is required from the legal team. No issues have been raised to date to contest declarations of interest. In cases of complaints, Ctgb liaises with an independent external complaints committee. In the case of objections, they can be forwarded to an independent external Advisory Committee.

Objections, appeals and complaints

The procedures for considering complaints have changed since the last IVC visitation. Before 2018, the Ctgb had an internal complaints committee, but it was abolished and complaints are now sent to an external complaints committee at the NVWA.

The legal basis for complaints, objection and appeal is provided in the national legislation. An interested party seeking to object to an authorisation decision of the Ctgb must first follow the objection procedure, before going to court. Objections may be presented not only by the applicant, but also by other admissible stakeholders, e.g. an NGO. Since the last evaluation by the IVC in 2018, objections and complaints are still infrequent but numbers have reduced to some extent. It is important to note that cases are often not addressed in the year they were filed. This applies to both objections and appeals. Especially the recovery time of the appeal can be very long. In 2021 and 2022, the Ctgb took measures to eliminate backlogs and reduce external costs for appeals (by not hiring lawyers; instead, the Ctgb legal advisors have been trained to plea themselves). The backlog strategy of the Ctgb aims to prioritise the workload, and thus reduce the number of objections to the decisions.

The following tables show the numbers of objections, appeals and complaints and their outcome in the years 2018-2022.

Table 1. Numbers of objections and their outcome in the years 2018-2022

Year	Objections received	Completed	Outcome
2018	35	30	well-founded: 5 partly well-founded: 6
2019	37	38	well-founded: 1 partly well-founded: 4
2020	27	33	well-founded: 5
2021	22	46	well-founded: 3
2022	23	35	well-founded: 4 partly well-founded: 2

Table 2. Numbers of appeals and their outcome in the years 2018-2022

Year	Appeals	Completed	Outcome
2018	3	7	well-founded: 5
2019	7	7	well-founded: 1
2020	10	8	well-founded: 1
2021	10	14	well-founded: 5
2022	6	10	well-founded: 0

Table 3. Numbers of complaints and their outcome in the years 2018-2022

Year	Complaints	Outcome
2018	1	Received as complaint. Forwarded as appeal. Outcome appeal: unfounded
2019	0	
2020	0	
2021	1	unfounded
2022	0	

Citizens' right to know

In the Netherlands, the new Open Government Act (Wet open overheid, Woo, NL 2021) came into effect in May 2022, safeguarding the citizens' right to know. The new legislation regulates public access to government information. Information requests frequently need interpretations by the legal team in cases where the Ctgb is the data owner. The law aims to provide high transparency by requiring governments to actively disclose information. Natural and legal persons can request access to public sector information without declaring specific interest in this information. Some 5-7 information requests per year also come via the European Commission for permission to provide information to third parties. The law contains absolute and relative exemptions to the obligation to provide information.

However also under the law, access to environmental information requires a more transparent regime for disclosing information. Between 2019 and 2022, 5 to 8 disclosure requests were received each year, some of them very large thus requiring a heavy workload.

Training of the legal advisors

It is noted by the IVC, that in the law schools of universities the core lawyer education does not cover the PPP and BP legislations, therefore it is necessary to strengthen the specific professional expertise of legal advisors through learning by doing. The senior colleagues of the legal team are mentoring younger colleagues within the team. The joint workshops of legal advisers of EU Member States are valuable for exchanging views and knowledge. The Ctgb has been very active in organising and participating in such workshops. Also networking with the academic world, for example, the neighbouring Wageningen University could be an option to keep the knowledge of the legal team updated about developments within this specific area of legislation.

RECOMMENDATIONS

8. **Networking locally with Wageningen University, and university experts in general is recommended for deepening and strengthening the expertise of the legal team on issues relevant to the PPP and biocide legislations.**

Scientific assessment procedures and delivery

The IVC was requested to address the scientific quality of the Ctgb processes related to the authorisation of plant protection products and biocides. In particular this section of the report focusses on:

a) the overall scientific and technical quality of the risk assessment documents that are prepared by the secretariat to substantiate the subsequent formal decisions by the Board;
b) the (internal) evaluations of submitted dossiers by Ctgb assessors with a focus on the identification of scientific excellence and consistency, particularly when dealing with gaps and ambiguities in the assessment framework, data interpretation and conclusions; and
c) progression in new scientific developments.

The evaluation covers both the national assessments, including mutual recognitions, and those conducted in the EU context, including the Ctgb contributions to EU assessments of pesticide and biocide active substances and the zonal assessments for PPP.

In the Ctgb webpage, the applicable assessment frameworks are presented in a clear and transparent way. The scientific assessments are described in Evaluation manuals, prepared by Ctgb and which have been frequently updated during the 5 years covered by the IVC evaluation. Evaluation manuals updates are described and justified, with clear indication on the applicable time window for each version.
The approach followed by the Ctgb when drafting the Evaluation manuals has been to include national and EU assessments in a single manual; highlighting, and justifying, the use of different approaches for the scientific evaluations at national and EU level when needed. The IVC fully supports this approach, which provides clarity to applicants and third parties and also facilitates the internal process for ensuring scientific consistency in the different assessment frameworks, while maintaining the regulatory and scientifically based differences.

The manuals reflect the complexity of the scientific assessments for pesticides and biocides, complementing the guidance documents with clarifications. During the evaluation, the IVC confirmed the overall excellent quality

of the manuals, which among others provide comprehensive clarifications for inconsistencies and recommendations for elements not covered in the EU guidance documents, Central Zone agreements for PPP assessments, the NL position in case of no agreement, acceptance of OECD draft guidelines, proposals for addressing flaws in the guidance documents, as well as pending issues. As a minor issue, the IVC observed that some scientific updates were mentioned on the website but not yet incorporated into the manual. In addition, new guidance documents, such as the updated EFSA guidance on the risk assessment for birds and mammals, published in February 2023, but not yet taken note of, are not mentioned. The IVC sees benefits in mentioning in the Ctgb manuals these guidance documents as soon as published by EFSA, adding a clear indication that they have not yet been formally implemented as regulatory guidance. This advanced reference would alert applicants to imminent obligations, and also these documents frequently provide important solutions to some of the scientific inconsistencies and missing elements identified in the previous versions. This aspect is clearly useful even before the formal adoption as regulatory guidance. For these reasons, in the opinion of the IVC, it would further increase the quality of the Evaluation manuals to mention newly published guidance documents and tools, and even those that are under update, e.g., at the phase of public consultation, with a note indicating that even not yet formally implemented in the regulatory context, these could provide updated and useful scientific views on some issues.

In addition to the Evaluation manuals, Ctgb scientific teams have developed complementary tools for ensuring consistency during the scientific assessments. Some are generic while others seem to be Team specific. During the evaluation the IVC was provided with evidence confirming the implementation of several consistency check tools, including the principle of internal review of the draft evaluations during the scientific assessment, or communication within the Team of scientific discussions going on at EU level.

In order to assess the scientific excellence and consistency of Ctgb assessments, the IVC developed a conceptual approach for the prioritisation and selection of dossiers for detailed scrutiny. This was later adapted in line with the scientific assessments conducted during the five years covered by this evaluation. The prioritisation included the following elements:

a) comparison of EU and national assessments for the same active substance, covering active substances for which the Ctgb acted as rapporteur and those for which Ctgb role was to comment during the EU process,
b) implementation of risk mitigation issues during the national assessment,
c) comparison of PPP and BP assessments for the same active substance,
d) assessment of issues of specific scientific or societal concern.

The IVC also decided to conduct separate assessments for conventional chemical substances, excluding basic substances and others with anticipated low hazard, and for microbial and other substances covered by the Green Team. For conventional chemical substances, the ideal situation should have been to select assessments covering the full process (i.e., for PPP the following processes: a.s. EU assessment; EU approval decision; MS PPP zonal and national assessment; and PPP national authorisation). However, due to delays in the EU process, it was not possible to identify a single conventional a.s. fulfilling these requirements in the 5 year review period. As indicated by Ctgb and confirmed in the EFSA and ECHA webpages, the Ctgb RMS assessments on conventional chemical pesticide a.s. with interest for this scientific assessment finalised in 2018 and onwards were still pending from the EFSA Conclusion and approval decision at the time of assessment (note that the EFSA conclusion on flutolanil was published on 7 June 2023). In addition, no CAR's for biocidal a.s. were finalized by Ctgb in the period covered by this report.

Therefore, the intended approach was adapted, and the evaluation of the IVC's scientific assessment procedure included the following steps:

- Comprehensive assessment of a limited set of a.s. and product dossiers, including the decisions of the Board concerning these products, following a similar approach to that in the previous evaluation (see annex 11 on sanitised dossier assessment for details)
- Detailed evaluation of the Ctgb manuals and assessment frameworks, identifying sets of key elements to be examined for evaluating both scientific excellence and coherence
- Selection by the IVC of some specific dossiers on a.s. and products for detailed focused assessments

for ad hoc confirmation of the scientific quality, transparency of the scientific assessments, and actual implementation of the scientific assessment procedures described in the manuals
- Additional confirmation of selected key elements on recent and ongoing assessments identified by the Ctgb staff during the face-to-face interviews with the IVC

For implementing the first and third points mentioned above, the IVC selected a set of dossiers from the list of applications compiled by the Ctgb in the document List of Product Authorisations Granted by Ctgb since 2018. The selected dossiers for detailed ad hoc assessment included:

- Assessments of chemical a.s. with Ctgb acting as RMS, covering renewal of existing substances, amendments of approval conditions, and assessments of new active substances
- Commenting rounds of EU assessments of pesticide chemical a.s. focusing on the comments submitted by Ctgb
- EU assessments of biocidal a.s. commented on by Ctgb covering the following categories PT 1, 2, 3, 4, 5, 6, 14 and 19
- Assessments of PPP for zonal and national assessments with Ctgb as zonal RMS and with Ctgb commenting on other assessments
- National assessments of PPP and biocidal products (BP) containing the a.s. selected above
- Specific attention was paid to comparative assessment of Candidates for Substitution and possibilities to substitute any uses of them.

For implementing the fourth point mentioned above, during its interviews with Ctgb scientific staff, the IVC presented a set of elements related to the scientific assessment extracted from the manuals and asked the staff to present evidence on the actual implementation of these elements in ongoing or recent assessments. In this case the dossiers were selected directly by the interviewed staff, using examples from their own evaluations, as expert or as internal reviewer. The focus was on national and zonal assessments of PPP and BP, including BP authorisations under the transitional legislation, in some cases with additional confirmations in the EU assessments.

RECOMMENDATIONS

9. The IVC recommends to further increase the quality of the Evaluation Manuals by mentioning newly published guidance documents and tools, including those that are under update, e.g., at the phase of public consultation, indicating that even not formally implemented they could provide updated scientific views on some issues.

National

The IVC mandate included the assessment of scientific excellence and consistency between the national and EU assessments. As explained above, the manuals and assessment frameworks present in a clear and transparent way the specific methods, tools and approaches which should be implemented for the national assessments. In line with the mandate, the IVC focused its assessment on the clarity and transparency of the process, not entering into detailed scientific evaluations of the provided justifications; nevertheless, the IVC observed that the national provisions are focused on the expected elements, in line with the regulatory frameworks, pertinent to the specific agricultural and environmental conditions of the Netherlands.

The IVC have not detected inconsistencies with the procedures, or issues of concern in the evaluated scientific assessments. The internal documents examined by the IVC confirm that in case of deviations among the national, zonal and EU assessments, the relevant assessment framework has been followed by the Ctgb scientific staff and is transparently reported. No deviations were identified in the assessed dossiers. As already indicated the integration of the different assessment frameworks in the same manual facilitate this process and is supported by the IVC. The internal documents have also provided evidence confirming the implementation of the internal processes for reviewing and commenting. The DMS keeps an excellent archive of the assessment process, from both procedural and scientific standpoints, including early drafts with comments from the reviewers and the responses from the assessors, the exposure estimations with the raw data and calculations, internal correspondence, and other relevant information. The IVC also acknowledges that the Ctgb public database

on product authorisations includes links with access to the Ctgb scientific evaluations in English.

One element for possible consideration by the Ctgb is the need to use in the national assessments, parameters and values from previous assessments, even knowing that they may no longer be scientifically valid and need to be updated. For example, in the assessment of the PPP Film, dated September 2022, the Ctgb used fate properties for flutolanil, such as the Koc, from the previous regulatory assessment, while in the EU renewal proposal, Ctgb had proposed that the updated values should be used. These updated values were finally confirmed in the recent EFSA Conclusion.
The IVC is aware that this is the approach to be followed in accordance with the current regulatory framework, in order to provide procedural clarity and predictability to applicants. However, it should be noted that the regulatory frameworks also include specific timelines for the assessments and renewals, that for different reasons, which are not under Ctgb's control, are extended largely exceeding the expectations of the regulations. In addition to the "stop the clock" previous possibilities, Commission Implementation Regulation (EU) 2018/1659 (EU 2018) has included an additional postponement for assessing the endocrine disruption potential, with a clock stop of up to 30 months for generating the necessary information. The consequence is that this disturbance, i.e., national assessments conducted with no longer valid core data, is not limited in time to relatively short periods, as expected in the regulations, but is prolonged for several years. In some situations, the updated values may influence the conclusions, creating the dilemma of providing marketing authorisations based on values that are no longer supported by the updated scientific assessments. During the IVC's personal interviews Ctgb scientific staff were questioned and the responses confirmed that when the scientific staff identify a clear concern, the Ctgb procedure would facilitate that the Board is properly informed. However, it was also clarified that it is not standard practice to conduct the assessments with both values in the case of updates during scientific processes prior to the formal regulatory decision.

RECOMMENDATIONS

10. **The IVC recommends that Ctgb further consider establishing a mechanism for alerting the Board in cases where the use of the updated values could lead to a different conclusion. Management options may include proactive measures and opening a dialogue with the applicant and proposing voluntary measures when concerns for human health or the environment are expected from the updated scientific assessment.**

Collaboration within EU

Ctgb's key role in the EU assessment of pesticides and biocides covers participations as RMS, CoRMS, zonal RMS, and contributor in the commenting process organised during the EFSA, ECHA and zonal assessments. The information provided by Ctgb as well as the information publicly available in the web sites of the European Commission and the European Agencies confirms this very significant involvement. The Netherlands has established a political priority for facilitating a market transfer towards green products with assumed less risk, which obviously has affected Ctgb priorities and working practices (see specific section on the Green Team, page no.28).
This prioritisation can be clearly observed in the selection of active substances for which Ctgb is approached as RMS. Cgtb does not actively select, but applicants prefer to submit their dossier to the NL because of their excellent expertise. Nevertheless, the IVC has also confirmed that despite this prioritisation, during the evaluated period Ctgb has also covered some conventional chemical a.s. and has maintained the effort for commenting on the EU assessment of conventional chemical pesticide and biocide a.s.

RECOMMENDATIONS

11. **The IVC fully supports this approach, and recommends Ctgb to maintain this dual effort, leading the development of the scientific assessment methodology for new categories of innovative green a.s., to confirm the assumption of low risk, while keeping the Ctgb commitment and contribution to the EU assessment of conventional a.s. This is not only needed to maintain the high reputation achieved by Ctgb in the EU process, but also for maintaining the excellence of the scientific assessments at national levels, as most product authorisations, currently and still in the coming years, are expected to be related to conventional a.s.**

During the detailed focused assessments of a.s. dossiers, the IVC confirmed the consistency and scientific excellence of the Ctgb assessments. The Ctgb assessments are conducted in line with the relevant EU procedures and are comprehensive and transparently reported. The responses to the comments received from others are properly addressed, and incorporated in the following versions of the assessments. The internal documents also provide evidence confirming the implementation of the internal processes for reviewing and commenting as already mentioned for the national assessments, extended in this case to consultations with the RIVM regarding the justified proposal for classification and labelling under the CLP Regulation. The DMS holds an archive of the assessment process, procedural and scientific, including early drafts with comments from the reviewers and the responses from the assessors, the exposure estimations with the raw data and calculations, internal correspondence, and other relevant information.

Regarding the Ctgb participation in commenting rounds, the IVC confirmed by accessing the commenting tables that in general the Ctgb comments are relevant, well justified and clearly presented. The accessed internal documents show Ctgb's efforts to facilitate the commenting process, including additional detailed indications for the experts regarding the process and the expectations.

Overall, the publicly available and internal evidence analysed by the IVC indicates that during the evaluated period the Ctgb has maintained a very high level of scientific excellence in their assessments and is a key contributor to the EU assessment processes for pesticide and biocide a.s. and products.

Contribution to scientific and methodological development

Regarding progress in the scientific assessment methodology, the Ctgb has prioritised the development of methodologies for assessing green products. This prioritisation has impact on the Ctgb contribution to other scientific developments, nevertheless, the information confirms Ctgb's participation in several guidance and methodological processes at EU and zonal level. An element to be further considered by Ctgb is that the tasks and responsibilities of Ctgb regarding national, zonal and EU assessments are based on the regulatory application of scientific knowledge. As scientific knowledge relevant for pesticide and biocide risk assessment is continuously evolving, Ctgb requires a long/term strategy to ensure that the capabilities of the scientific staff are maintained and updated.

The approach implemented in the Netherlands is based on the collaboration of Ctgb with research organisations, in particular with RIVM and Wageningen University and Research (WUR). During the evaluation, the IVC received evidence covering some collaborative projects, confirming the participation of Ctgb scientific staff. The role of the Ctgb staff depends on the project, but in some cases the role was only tangential, as a future user of the tools and methods to be developed, and the IVC deems that higher involvement could have been beneficial. While the role of researchers is different from that of regulatory scientists, both are equally needed for developing tools and methods for risk assessment. Ctgb scientific staff gain highly valuable scientific knowledge through the assessment and expert discussions, and the workplans should consider that participation in these projects is not only beneficial in terms of personal and institutional recognition, but a key element for ensuring that research and innovation are adequately integrated in the risk assessment methodology.

RECOMMENDATIONS

12. **The IVC recommends that the Ctgb workplans should balance short and long term needs and provide Ctgb scientific staff with sufficient time to contribute to the update of the risk assessment methodology. Specifically Ctgb should further develop the collaboration with RIVM, WUR and other research institutions to maximise the use of the accumulated Ctgb scientific knowledge on risk assessment.**

Issues – lead-times and delays

Delays and lack of capacity for respecting the timelines established for the different steps of the scientific assessment for PPP and BP is, unfortunately, a common situation at EU and national level, also affecting Ctgb. This is the consequence of a combination of different factors, some under total or partial control by Ctgb and others outside

the Ctgb remit. Ctgb has already addressed the internal issues in detail and started a process for re-organisation in order to improve efficiency, as detailed in the section on the new organisation (page 16). In addition to workload, staff allocation and efficiency issues, there are other factors to be considered. The IVC has identified two factors of specific relevance to be further considered by Ctgb in terms of efficiency estimation.

One is the continuously increased complexity of the risk assessment process. The number of guidance documents and tools is increasing, and the complexity and length of each guidance follows an exponential trend. Examples are the additional guidance on genotoxicity or the updated EFSA guidances on bees and on birds and mammals. This situation requires additional time to keep the staff updated. Considering the turnover of scientific staff, and the different uptake of guidance and methodologies for the different EU, zonal and national assessments, this is particularly relevant for new staff who should be trained in both the previous and the updated methodologies applied to different assessment frameworks.

The second factor is the additional timelines between the internal steps of the risk assessment process. All assessments are iterative by nature, the internal iteration requires effective communication between different Ctgb experts, offering Ctgb the possibility to further improve the internal process, while the iterations with external actors, such as the applicant, MSs and EU agencies, are mostly outside Ctgb control and requires the staff to put on hold the assessment, and restart the process after weeks, months or even years, e.g. following a 30 months' clock stop under Commission Implementation Regulation (EU) 2018/1659 (EU 2018).

RECOMMENDATIONS

13. **As a consequence of the combination of both factors, during the planning stages of the scientific process, the time allocated to the actual assessments and the time allocated to ensure that the staff is updated and knowledgeable, should be reassessed for the different processes, areas and seniority levels on a regular basis. If necessary, the workplans and assignments should be revised. This process will ensure that delays related to increased scientific or procedural complexity are not misunderstood as a lack of efficiency.**

Informing the Commission and the other Member States about unexpected harmful effects

A general assumption is, that based on the risk assessment and risk management, an authorised product is safe, if used according to its use instructions. Nevertheless, new information can emerge about unexpected harmful effects. In that case, the Ctgb receives a notification from an authorisation holder, a third party such as the NVWA, the Environment and Transport Inspectorate (ILT), the National Poisons Information Centre (NVIC) or a user of a product. New information can also be published in scientific papers or newspapers. Notification concerning new information (Article 56 Reg 1107/2009 (EU 2009) and Article 47 Reg 528/2012 (EU 2012)) which must be investigated to assess whether there is a risk not foreseen in the original evaluation, with the conclusion that the authorised product no longer complies with the requirements. In cases where it concerns new information about the substance, Ctgb shares it with the Commission and other Member States.

If the new information indicates unforeseen risk, the Ctgb asks the applicant to submit a request to change the conditions of authorisation. If the changed conditions of authorisation can solve the problem, no notification is required to other Member States and the Commission. If the applicant does not want to submit a change request, then the Ctgb intervenes in the authorisation. Ultimately, such new information may even lead to the authorisation being withdrawn. A process for such notifications is in place at the Ctgb, and the Reports Information Coordination Team (MIC) team is responsible for processing a wide range of new information. Since 2020, about 20 notifications were received that concerned the above-mentioned Articles.

Based on the evaluation of the procedures of notification, the IVC appreciates the effort of the Ctgb to timely inform the other Member States and the Commission on unexpected harmful effects of biocides and plant protection products and considers the procedures of notification functioning well within the Ctgb. This is a good example, where the Ctgb is a forerunner in sharing new information within the EU Member States. The IVC suggests that the Ctgb maintains in its new organisational structure the MIC team to actively search and process new information about PPPs and biocides to share with other Member States and the Commission.

The Green Team

The "Green Team" is a special group within the Ctgb assessment structure, that takes the lead on active substances and products, mainly PPPs, based on microbials as well as other "green" (e.g., botanicals, pheromones, peptides) active substances and products.

The Team has a strategic role: within the framework of the EU Green Deal, that calls for halving the use of chemical pesticides by 2030, the national Vision for the Future of Plant Protection (NL 2023) highlights the importance of promoting the use of "green" PPPs. Stakeholders' interest has also been demonstrated by the attendance at the workshop dedicated to the new assessment framework of "green" PPP: the event was organised by the Ctgb on November 2022 and involved more than 50 participants, both manufacturers and consultants from the Netherlands and elsewhere in the EU. The IVC notes that the Netherlands was the first Member State to hold a workshop on the new dossier requirements. In accordance with the requirements by policy makers, the Ctgb's long-range strategy envisages a priority pipeline for the assessment of microbial and "green" dossiers. This is reflected by the fact that the majority (approximately two thirds) of pesticidal substances for which Netherlands is rapporteur or co-rapporteur in the EU (29 in 2022) consists of microbials (viruses, bacteria, fungi) and other "green" a.s. such as plant extracts and peptides.

The assessment of microbial pesticides requires different expertise compared to the conventional chemical substances. The Green Team possesses all the relevant expertise. For highly specific expertise that is not available in house, the Team can approach RIVM. The IVC staff interview revealed that the Team is highly committed and aware of its strategic role. The Team showed to be most enthusiastic about the new ways of working and the re-organisation of Ctgb into dossier-targeted transdisciplinary teams; the new re-organisation, indeed, will facilitate the Green Team to cope with the increasing workload by gathering expertise from other Ctgb colleagues.

The expertise and commitment of the Green Team is highlighted by the role of Ctgb in the discussion of the scientific criteria in the new (September 2022) EU regulation on the microbial active substances and PPP (EU 2022 a, b, c). The Team has shown their strength for the assessment of "green" pesticides and as a result the team has been appointed to the EU peer-review process. The IVC suggests that Ctgb continues its efforts to update the guidance documents for microbial pesticides, exploiting and developing further the significant expertise and experience gained to date.

The prowess of Ctgb on microbial pesticides was also indicated by the correspondence and documents concerning the Peer review of the pesticide risk assessment of the active substance *Cydia pomonella* granulovirus (EFSA 2022), where the Netherlands acted as co-rapporteur Member State. Here the Ctgb experts actually carried out a large part of the work, in particular the environmental fate and behaviour and the ecotoxicological risk assessment.
The IVC commends the activity of the Green Team also because it marks the Ctgb's proactive role toward the EU Green Deal. Meanwhile the IVC wishes to emphasise that the prioritisation given to the "green" a.s. should not weaken the assessment of the "conventional" chemical PPPs and BPs: these will remain an important component of the EU regulatory framework, hence Ctgb should maintain its current high-rank work on chemical PPP and BPs.

RECOMMENDATIONS

14. **While the IVC commends the priority pipeline for "green" substances, attention should be given to maintaining the current assessment capacity toward "conventional" chemical PPP and BP. Furthermore, the IVC suggests that Ctgb continues its efforts in updating the guidance documents for microbial pesticides, exploiting the significant experience gained to date.**

Contribution to the sustainable use of pesticides

The Netherlands' new Vision for the Future of Plant Protection (NL 2023) provides guidelines on the Dutch policy on the sustainable use of pesticides. It highlights very much the importance of integrated pest management (IPM) to reach its strategic goals for building resilient cropping systems. In the multiannual strategy of the Ctgb sustainability is highlighted by prioritising assessments of "green" dossiers and strengthening the capacity of the green team in microbiological knowledge. In fact, the NL is the leading Member State in charge of evaluating microbial

active substances acting as the RMS for circa every third microbial PPP active substance dossier in the EU, and thus enabling alternatives for chemicals to be on the market. In the staff interviews the planned new organisation structure of multidisciplinary teams was considered to be a strong asset for delivering expectation on Sustainability.

Ministries of the Environment and Agriculture are responsible for the Netherlands' opinions concerning the sustainable use of pesticides (Directive 2009/128/EC (EU 2009 b) and the Commission proposal for the regulation, (EU 2022 d), including IPM issues, but the Ctgb is consulted in the interministerial negotiations. As integrated pest management (IPM) options are not under the direct responsibility of the Ctgb, it cannot take decisions on alternative methods to be used. It is up to the user to decide, which risk mitigation measures best fit specific use conditions

Comparative assessment

The Ctgb admits that conducting comparative assessments is a big challenge, as do all Competent Authorities within the EU Member States. For PPP the procedures of comparative assessment were introduced in the Ctgb in 2016, and the processes are under current development. The layout of the 'NL addendum CA' contains the comparative assessment prepared by the applicant, the NVWA's integral comparative agronomic assessment and the conclusion prepared by the Ctgb. An improved format for the 'NL addendum CA' is in preparation, where the applicant's version is the starting point, and where comments from the NVWA (in case of PPPs) and RIVM (in case of biocides) as well as those from the Ctgb can be displayed, as is customary in other parts of the assessment report.

In practice, comparative assessment has not led to any substitution yet, because the risk assessment schedules of alternatives are not aligned with the assessments of the candidates for substitution. When the agronomical comparison identifies sufficient full alternatives that require a comparative risk assessment, this can only be performed when the standard risk assessment for the alternative has been finalized. No examples where the substitution is possible to implement could be given, due to the limited availability of different modes of action. The situation is similar for almost all MS.

The EU Commission concluded in the REFIT-evaluation of the PPP regulation that the comparative assessment is neither effective nor efficient. In 2021 the Commission started an EU working group to prepare a proposal to improve the criteria and guidance document for comparative assessment. The NL has actively contributed to this work using the expertise of the Ctgb. The Ctgb has provided the Commission with input to improve the system. This effort is acknowledged by the IVC members.

The Ctgb highlights the weaknesses of the procedure: comparative assessment is difficult to implement in practice. The IVC questions if it is possible to determine whether the suitable alternative product or method, if available, is significantly safer than the product based on the candidate for substitution. Since the alternative product is usually on the market for many years, the risk assessment was performed according to older guidance documents and data requirements. The new product is assessed according to the latest guidances. A complete risk assessment of the alternative in accordance with the latest guidance is usually not possible due to the lack of data and would have a prohibitive workload. Even if such a comparison could be made, it is unclear how differences need to be weighed, e.g., if a product is less of a risk to the environment, but more of a risk to the operator compared to another product, which product is significantly safer? Ctgb is seeking a more pragmatic, less laborious way of making the required comparison. Practical choices regarding the execution of the comparative assessment are also being evaluated and the Board will be advised to make some adaptations.

In the onsite interviews it was noted by the IVC members that the agronomic expertise of the appropriate scientific assessors to consider non-chemical alternatives to pesticides is not as deep as Ctgb's expertise in other areas of risk assessment. The Ctgb is largely dependent on the expertise of the NVWA or the RIVM in questions dealing with comparison of viable alternatives. The situation is similar in all Member States and the effective implementation of the substitution principle is hampered both in PPP and biocide authorisations.

RECOMMENDATIONS

15. **The IVC recommends that Ctgb ensures that it has adequate number of scientific staff with enough expertise and knowledge for the comparative assessment of alternative nonchemical methods for controlling pests, weeds and diseases both in agricultural and biocidal use situations, including the socio-economic analysis.**

Stakeholders' views

Ctgb is an independent authority (in Dutch ZBO) which performs public service tasks but operates independently and not under the direct authority of a Dutch ministry. As such it must be evaluated every five years for its efficient and effective functioning under the ZBO Framework Act (wetten.nl - Regeling - Kaderwet zelfstandige bestuurs-organen - BWBR0020495 (overheid.nl)).

The IVC was given access to a report for the period 2016-2020 which was commissioned by the Ministry of Agriculture, Nature and Food Quality (LNV) from Andersson Elffers Felix (Doelmatigheidsonderzoek 2016-2020 - AEF - Deskundig en onafhankelijk onder toenemende druk, AEF 2022), and is based on information, interviews with Ctgb and the ministries involved and focus groups with relevant external stakeholders. The Dutch document was Google translated.

The IVC agrees with the report's principal conclusion that Ctgb generally functions efficiently and effectively in its risk assessment processes, its provision of policy advice and cooperation in the EU. The report recognises the pressures and challenges to Ctgb's performance arising from the increasing workload and the increasing time required to process applications. Much of this is beyond Ctgb's control arising from the European legislation. Also acknowledged is the importance of recruiting and retaining suitably qualified staff and the continued need for communication about the authorisation decisions to producers and other stakeholders. The IVC strongly agrees with this conclusion.

During its mission, the IVC2023 has examined a large amount of written documents and interviewed a significant number of staff at all levels. Based on the substantial information gathered, the IVC2023 is very pleased to confirm that the Ctgb is a high delivering regulatory organisation with a strong scientific core. The IVC is also very grateful for the unlimited access and assistance provided by the Board, Management and staff of the Ctgb during its work both on and off site.

The current IVC appreciates that most of the recommendations of the two previous visitations have been implemented by the Ctgb which continues to build for the challenges ahead. The Ctgb operates at an excellent scientific level, a conclusion supported by the quality and consistency of its assessments and its influential contribution to the commenting phase at EU level. The scientific work of the Ctgb and its outcomes are of good quality and largely appreciated within the community of risk assessors and risk managers within the EU Member States and internationally. A highly positive and recognised aspect is the significant contribution to the development and harmonisation of EU and international guidance documents. Ctgb's internal Evaluation manuals are another valuable aspect, as they are clear, detailed and up-to-date, and unified for EU and national assessments (PPP chemicals: Evaluation Manuals | Plant Protection Products | Board for the Authorisation of Plant Protection Products and Biocides (ctgb.nl) PPP biopesticides: Evaluation Manual Biopesticides | Plant Protection Products | Board for the Authorisation of Plant Protection Products and Biocides (ctgb.nl) Biocides: Evaluation Manual | Biocides | Board for the Authorisation of Plant Protection Products and Biocides (ctgb.nl)).

The IVC suggests that these Evaluation manuals could also refer to new guidance documents and tools that are still not formally implemented (e.g., at the phase of public consultation) as the manuals will then provide updated scientific views on some issues. The IVC also notes a possible issue when time schedules for the assessment of national products may lead to the use of parameters that are superseded at the EU level: the IVC recommends that a mechanism be established within Ctgb for alerting the Board in cases where the use of the updated values could lead to a different conclusion.

The Ctgb, in accordance with the national NL policy and the expectations of the EU Green Deal, provides a priority

pipeline for “green” products, such as products based on microbial pesticides. This is clearly demonstrated by the applicants’ selection of Ctgb to acts as RMS for a.s. at the EU level, as well as by the creation within the Ctgb of an enthusiastic and talented Green Team to deal with the assessment of such substances. Meanwhile, Ctgb also shows commitment, both as RMS and through the commenting phase, to conventional chemical a.s., which still represent the majority of pesticide and biocide a.s. under assessment in the EU. The IVC fully supports this dual approach, and commends Ctgb for maintaining attention to both green and conventional a.s..

Considering the turnover of scientific assessors, a vital point in order to maintain and improve the Ctgb’s existing high standard and reputation, is the recruitment and retention of suitably qualified and trained staff. Additionally, opportunities for personal career growth within the Ctgb such as the creation of new positions could possibly reduce the turnover of staff and attract new motivated personnel.

Overall, staff involved in risk assessment are well-qualified and show the required range of multidisciplinary expertise; however, in a number of cases the IVC could not complete a full appraisal of the expertise, because the available information in the CV's is very limited and incomplete, a point needing improvement.

From the organisation standpoint, the Ctgb has withstood well the disturbing and prolonged impact of the Corona pandemic. Indeed, the whole management and all staff are to be congratulated for their combined efforts and new ways of working which resulted in very few practical delays in delivering the extensive work program. Based on this positive experience, Ctgb has organised and put in place a highly effective hybrid working program.

Although Ctgb’s imminent organisational change was not formally within the terms of reference of this evaluation, the IVC recognized the strong motivations behind it:- namely, efficiency, and in particular time-effectiveness, and improving interdisciplinarity and optimisation of working according to the process flow. The IVC also noted that the majority of staff were very positive about the oncoming changes. Overall, the IVC is favourably impressed by the open and collaborative attitude, by the culture of collegiality permeating the organization as well as by the determined effort to promote external and internal training and personnel development. In addition, the IVC found Ctgb’s internal communication policy to be appropriate, clear and effective; it should continue to be pursued with determination, taking care that all employees have the possibility of receiving and seeking information and answers. Meanwhile the IVC recommends that clear and transparent criteria are publicised for the promotion of staff to management and/or senior scientific positions, and suggest the establishment of a future parallel career path for scientific staff, which does not require senior scientists to apply for managerial positions in order to progress professionally within the Ctgb. The IVC also supports the current DOI policy and recommends that its implementation should be maintained in the future.

The Ctgb satisfactorily complies with the requirements of relevant EU and national legislation in its regulatory work and provides the NL policy makers with valuable scientific and technical support. At the same time, the IVC recognizes that Ctgb shares with the other MS authorities problems relating to the increasing complexity of the legislative requirements at the EU level. A competent legal team deals with objections, appeals and complaints. Well-founded decisions with clear arguments contribute to better acceptance by the applicants and general public, thus leading to fewer numbers of objections. However, as the handling times of objections and court cases are usually long, the IVC’s evaluation window may not be long enough to show a consistent reduction yet. Since the PPP and BP legislations are continually evolving and increasing in their complexity, networking with other legal expert groups including academics could clearly help the work of the Ctgb legal team by increasing contact with wider expertise.

The commendable initiatives taken by the Ctgb within the EU regulatory community, for instance informing other Member States and the Commission without delay about unexpected harmful effects of plant protection products and biocides, are acknowledged by the IVC. In addition, the IVC supports the Ctgb commitment in the recent (2021) EU working group on alternative non-chemical methods for pest control and recommends that Ctgb ensures having sufficient scientific staff available with relevant expertise.

In accordance with the EU framework, openness and transparency are key principles in risk communication and in the appropriate exchange of timely information: both build trust. Ctgb commits a lot of effort to achieve a high

degree of transparency and openness by providing proactive, transparent and open communication to all interested parties. The external communication policy is also proactive and effective. For example, information on the website is available, easy to find and user friendly, stakeholders are identified and targeted and there is a good attention paid towards risk perception. The IVC suggests that interactive events organised with target groups could provide additional benefits, in particular regarding relationships with NGOs.

To conclude, the IVC considers that the Ctgb is run well as a strong and effective regulatory agency that has significant resources and capacity to respond to the expectations of applicants and both national and European society. A follow-up visitation in a few years is recommended in order to monitor the impact of the re-organisation and new ways of working.

Acknowledgements

The members of the IVC are extremely grateful for the kind support and assistance offered by the management, the Board and all staff members that we talked to during our site visits and also in online follow ups. Thank you all for your time and patience. In particular the IVC would like to thank Dr Rob van Lint, Chairman of the Board, the members of the Board, particularly Prof. Herman Eijsackers, and Dr Ingrid Beck-Vermeer, Executive Director and Secretary to the Board. The IVC also appreciated the unrestricted access to all the information that we wanted to look at, and in some cases guidance and help to get through to it.

The IVC could not have undertaken its tasks smoothly without the frequent help, support and practical arrangements provided by Dr Sjon Kortekaas. Thank you Sjon for the life belts that you threw us when we got into IT difficulties. We would also like to thank Eva Solinger for all her help with our travel, welfare and accommodation arrangements.

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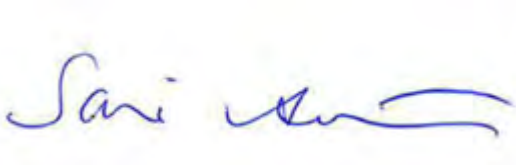
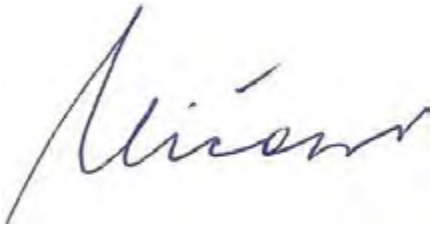
Statement Of Commitment

Dr. Anthony Richard Hardy, United Kingdom (chairman)

Dr. Sari Autio, Finland



Dr. Elizabeta Mičović, Slovenija



Dr. Alberto Mantovani, Italy

Prof. José V. Tarazona Lafarga, Spain

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Annexes

Annexes: Table of contents

Terms of Reference for the IVC2023

Terms of Reference - Visitation Ctgb 2023

Objective and scope of the international visitation

1. The requirements imposed on competent authorities by the European Commission, the industry, politics 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 in assessment and decision taking, 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 plant protection products and biocides. In particular:
     - Quality: the overall scientific and technical quality of the risk assessment documents that are prepared by the secretariat to substantiate the subsequent formal decisions by the Board.
       Also the legal compliance of the evaluations, e.g. are they based on the applicable guidance documents?
     - 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.
       Also the legal compliance of the process, e.g. is it based on the applicable guidance documents? Compliance with legal deadlines?
     - Board: the contribution and role of the Board in the decision making process, in particular the level of competence and procedural aspects.
     - Existing authorizations and possible actualization with a view to developments in EU legislation (article 56, (EC) No 1107/2009; article 48, (EU) 528/2012)
     - Progression in new scientific developments.
   - Dealing with demands of all stakeholders (European Commission, ECHA, EFSA, Competent Authorities of other Member States, industry, general public) and apparently contradictory requirements, considering:
     - The requirements, procedure and timeframes for product authorisation as set out in the biocides ((EU) 528/2012) and the plant protection products regulation ((EC) No 1107/2009);
     - The need for transparency and the existing rules for disclosure;
     - 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.
     - 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.

- The legal timelines as laid down in the biocides and plant protection products regulations are not met by the Member States. Current practice and theory behind the legal timelines at the time of implementation of the regulations is diverging more and more.
- Role and contribution of Competent Authorities with regard to the European Green Deal, Farm-to-Fork strategy, EU Chemicals Strategy, National strategies, knowing that Competent Authorities are responsible for decisions on the **authorisation**, while the European and national strategies contribute to a reduction of the **use** of products.

3. The IVC is requested to make recommendations as it deems appropriate.
   - Indicators are i.a.:
     - Quality:
       - Level of expertise and experience of staff and the Board;
       - Scientific/technical quality of the assessment documents as prepared for the Board;
     - Process:
       - Documentation and transparency of the advisory and decision-making processes;
       - Compliance with legal timelines
       - ln-house management structure and responsibility levels, consultation and checks and collegial feedbacks;
     - Resources:
       - Extent of available assessment capacity;
       - Extent of available capacity for project management;
       - Extent of available capacity for policy advice, legal advice and internal and external communication;
       - Extent of available capacity in the supporting department (e.g. human resources, quality team, IT, finance).
       - Extent of involvement with developing the international risk assessment framework
     - The Board:
       - Assessment by the Board of the assessment 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.
     - External Constraints:
       - Legal
       - Procedural
       - Practical

The International Visitation Committee (IVC)

4. The proposed team will include 5 members with broad experience and expertise in the field of hazard and risk assessment and, jointly, in regulatory authorisation of plant protection products and biocides, from different EU-member states. 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 Dr. Tony Hardy (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 €660 per working day of 8 hours (with a maximum of 100 days for the whole assignment); 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. Ctgb requests to receive the committee's final report September 2023. The following timetable is proposed in order to achieve that:
   - the agreement of the Terms of Reference is reached in November/December 2022
   - the international visitation committee (lVC) is established in November/December 2022;
   - 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 2023

8. The committee is provisionally scheduled to meet (preferably face-to-face, but this might not always be possible) 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/ December 2022	Agreement on Terms of Reference (ToR) and the members of the committee
xx January 2023	**First meeting** of the international visitation committee discussing the Activity plan, strategy, tasks and timing
xx February 2023	Approval of the Activity plan by the Board. Activity plan indicates methodology and approach for the evaluation, including research questions and indicators. Access to selected dossiers/documents for review; list of IVC questions
Mid March 2023	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 2023	(virtual) Meeting of the IVC members: discuss progress, reviewing responses received from Ctgb, first impressions, assessment approaches, practicalities
May 2023	**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 2023	**Delivery draft report**, followed by Meeting of the Visitation Committee with the Ctgb management to discuss the draft final report.
xx September 2023	Formal presentation of the Final Visitation Report

Curriculum Vitae of members of IVC2023

Curriculim Vitae of members of IVC2023

Anthony Richard Hardy **October 2022**

CURRICULUM VITAE

Dr Anthony Richard Hardy

Telephone: +44 1428 609779
Mob: +44 7789 609784
e-mail: t.hardy91@btinternet.com

Home: 63 Kingswood Firs
Grayshott
Hampshire, GU26 6ER
United Kingdom

Career Resume

- originally trained in zoology and ecology, joined Ministry of Agriculture, Fisheries and Food as a research biologist
- 7 years as an environmental chemist developing field risk assessments and methods for determining the environmental impact of pesticides, links with registration department and industry
- developed expertise in ecotoxicology, 35 years of contributions as member of several national and international regulatory committees, initially pesticides (ecotoxicology and environmental impact) but since 1998 on wider food safety issues at National, European and wider International levels
- 3 years as senior manager leading research Mammals and Birds Department
- 2 years as Research Director of the ADAS Central Science Laboratory (forerunner of the MAFF Executive Agency Central Science Laboratory), then UK Ministry of Agriculture, Fisheries and Food became Department of Environment, Food and Rural Affairs (Defra)
- 17 years as Science Director (Agric-Environment) and Management Board/Leadership Team member at Central Science Laboratory contributing to and leading parts of change management programme, Agency launch, major relocation exercise and re-establishment at new laboratory site. Corporate responsibility for development of CSL agency and business.
- Interim Director of Centre for Low Carbon Futures, based at University of York, to establish the Centre, set up Company Limited by Guarantee, established funded pilot projects across Yorkshire Universities, developed profile and promoted cross-university Centre (York, Leeds, Sheffield and Hull Universities)
- Retired 2010

Career Summary

April 2009 – January 2010 Centre for Low Carbon Futures (University of York, UK) Interim Director

Tasked to set up the new Centre, establish it as a Company Limited by Guarantee, set up agreed cross-university pilot research projects, recruit research staff and core Centre staff, develop and implement communication plan, develop profile and promote the Centre, liaise with University senior academics, report to interim Board (Vice-Chancellors of Universities of Hull, Leeds, Sheffield and York, Yorkshire Forward and Yorkshire Universities), establish links with regional business community, develop corporate strategy and bids for external funding.

Ongoing April 2003 – April 2018
Independent risk assessment expert

Worked as an independent risk assessment expert with the European Food Safety Authority (EFSA), based in Parma, northern Italy. I chaired the Plant Protection Products and their Residues Panel (PPR Panel) and therefore was also a member of the senior cross-discipline Scientific Committee (9 years). In 2012 I was appointed directly to the Scientific Committee and have chaired it for 6 years. This required regular meetings in Italy, primarily Parma, but also in Austria, Belgium (Brussels), Denmark, France, Greece, Netherlands, Slovakia, Spain and Portugal and involved interaction with the senior management of EFSA and the European Commission.

April 1992 – 2009 Central Science Laboratory Sand Hutton Science Director (Agri- Environment) SCS JESP 11 (Band 1)

My job was divided into 3 main areas of activity and responsibility:

A) As Science Director (Agri-Environment) I was principally responsible for developing the science and the delivery of the work programme of the Directorate. This diverse programme covers sustainable land management, environmental protection, wildlife management and pesticide and disease impacts on wildlife. As part of the CSL Leadership Team, I had corporate responsibility for the strategic planning, leadership, management and operational delivery of the agency's overall work programme.

B) Appointed as an independent scientist to the risk assessment panels of the European Food Safety Authority, EFSA, I was elected Chairman of the Plant Protection Products and their Residues (PPR) Panel which primarily carries out risk assesments on pesticide dossiers and develops guidance on risk assessment. I was also a member of the EFSA Scientific Committee which sits above the Panels and operates across all disciplines. This activity required regular meetings in Italy and other Member States and frequent interaction with the senior management of EFSA.

C) Across CSL, I account managed the Defra R&D programme, interacted with senior policy customers in core-Defra and Science Directorate to establish, and deliver the programme and co-ordinate the delivery of the scientific project reports.

I managed 3 science groups (Plant Health Group, Wildlife Ecology and Management Group, Environmental Biology Group). In 2007-2008 for example I had budget responsibility for £24M and management responsibility for approximately 350 staff.

My personal Business and Development Objectives for year 2007-2008 were:

Defra – External liaison and delivery

1. Establish and maintain good working relationships with new and existing core-Defra policy Divisions, and Groups as the new structure of Defra emerges. Act as overall Account Manager for core-Defra customers.
2. Provide support to policy colleagues in core-Defra over advice to Ministers
3. Ensure that the 2007/08 Defra-commissioned R&D programme is on course for end-year delivery through regular monitoring during the year of scientific progress against resource, to achieve >90% milestones and to support policy outcomes as monitored by the customer satisfaction survey.
4. Contribute as required to core-Defra committees relating to CSL business e.g. Laboratory Advisory Board.
5. Establish, maintain and/or extend working relationships with other government organisations e.g.Scottish Office, SASA, SAC, Environment Agency, Natural England and Scottish Natural Heritage.
6. Maintain and extend contacts with collaborating public sector laboratories through the Interlab Forum, particularly VLA and CEFAS.
7. Provide support to CEO relating to the Defra Agency Review.

EU outreach

1. Chair the Plant Protection Products and their Residues Panel of the European Food Safety Authority and make full contribution as a member of the overarching EFSA Scientific Committee.
2. Maintain and extend links with EC staff in Brussels particularly in DG Research, DG SANCO, DG Agriculture and DG Environment to further business and scientific opportunities for CSL.
3. Keep an overview of CSL's Framework Programme research activities & database of developing proposals and bids.

CSL Management – Agri-Environment Directorate

1. Meet or exceed the business plan income for the Agri-Environment Directorate for 2007/078 (£24.4M) and deliver a contribution of £5.8M.
2. Monitor financial performance through regular meetings of A-E Senior Team, Operational Performance Meetings and Bilaterals.
3. Keep under review team structures and resources against income and strategically build areas for expansion e.g. sustainable land management, climate change, nanoscience and pharmaceuticals.
4. Deliver contingencies in year and review strategic capabilities within the Directorate.
5. Deliver agreed target publication rate for the Directorate of 150 papers submitted to Sci-search journals.
6. Manage Science Audit implementation plan in response to Audit recommendations.
7. Add high level strategic input to CSL's organisational and business planning processes and contribute fully to the CSL senior management committee – the Leadership Team.
8. Strategic oversight of CSL's seedcorn research and science network activities through management of seedcorn and network co-ordinator.
9. Regularly communicate strategic and corporate messages to staff within Agri-Environment Directorate and wider CSL.
10. Manage Account Management (and succession planning), produce structure plan and ensure training.

I had a leading role in the change management programme to change the culture of the Laboratory, prepare, restructure and reposition CSL for Agency launch in 1992 and relaunch in 1994 after enlargement (with the Food Science Laboratories). I played a prominent role during our major relocation exercise to York, including strategic planning and implementation, and drove the transfer of the science programme and re-establishment at a new laboratory at Sand Hutton to achieve minimum disruption to the delivery to our broadening customer base.
I was part of the CSL team working with external consultants through protracted prior options reviews of the agency (3 cycles) which challenged future ownership models.

- CSL Certificate Holder under Animals (Scientific Procedures) Act 1986 (covering all animal work carried out at or from Sand Hutton and Woodchester Park)
- I have Security Check (SC) clearance.

I most recently championed the CSL business expansion to enter the forensic market, leading the bid presentation which achieved inclusion to the National Framework Agreement with the National Policing Improvement Agency to enable CSL to tender for forensic service support, including DNA profiling, to the police authorities.

March 1990 To April 1992	**ADAS Central Science Laboratory**	**Research Director SCS (Grade 5)**

Fore-runner of current post, based at the Slough Laboratory, preparing for and launching the CSL Agency. Established the structure of new R&D projects and programmes as MAFF set up a new commissioning process following budgetary transfer to Policy Customer Groups in 1992.
Substituted for CSL Director (SCS, Grade 3) for 4 weeks in January 1993

February 1986 To March 1990	**ADAS Worplesdon Laoratory**	**Head of Mammals and Birds Department (Grade 6)**

Headed one of 3 science Departments which made up the predecessor of CSL and which occupied a main Laboratory near Guildford, with outstations distributed around England and Wales. Approximately 120 staff working on the management of vertebrates and the environmental impact of agriculture.

February 1983 To January 1986	**ADAS Tolworth Laboratory**	**Head of Environmental Chemistry Branch (PSO)**

Responsible for assessing the environmental impact of pesticides on wildlife.

September 1979 to February 1983	**Pest Control Chemistry Department Tolworth Laboratory**	**Senior Scientific Officer**

Appointed to the Environmental Chemistry Branch, established and led field team to develop methods and carry out field trials of pesticide impact on wildlife. Set up and coordinated multidisciplinary scientific research and monitoring studies within major and pioneering MAFF project at Boxworth Experimental Husbandry Farm in Cambridgeshire.This

investigated the environmental effects of different pesticide regimes at field scale of use for 10 years. I led the project on the ground and produced annual reports for the first 5 years.

For the first 3 years this was a joint post that was split between research at Tolworth and the Pesticides Registration Department at the Harpenden Laboratory (fore runner of Pesticides Safety Division) where I advised the pesticide industry on field trials and risk assessment of wildlife studies. I also was secretary and then Member of the Environmental Panel which advised the cross-Departmental Advisory Committee on Pesticides (ACP).

January 1976 **To August 1979**	**Rodent Research Department, Pest Infestation Control Laboratory, Tolworth**	**Higher Scientific Officer**

Joined the Ministry of Agriculture, Fisheries and Food to carry out field research on rat ecology and behaviour including reinvasion studies on farms after rodenticide use.

International Conferences and Overseas Visits

International conferences attended and papers presented in Belgium, Bulgaria, Canada, Denmark, Dominican Republic, Finland, France, Germany, Hungary, Italy, Luxemburg, Netherlands, Norway, Poland, Portugal, Russia, Spain, Slovakia, Sweden, Switzerland, Turkey and the United States. Member of three expert pesticide groups for FAO in Rome. Lectured in ecotoxicology on NATO Advanced Workshop in Italy. Study Tours to United States and Netherlands.

1996 Member of International Visiting Group to the EU Environmental Institute, Joint Research Centre, Ispra, Italy.

1999 and 2004 Member of external Science Audit Group for Centre of Ecology and Hydrology (CEH), NERC

2018 Member of International Visiting Committee to evaluate College voor de toelating van gewasbeschermingsmiddelen en biociden (Board for the Authorisation of Plant protection Products and Biocides) in the Netherlands.

Education

1972 BA (Hons) Zoology, Oxford University
1973 MA Zoology, Oxford University
1977 PhD Zoology, Aberdeen University
1995 Appointed Honorary Visiting Professor in Department of Applied Biology, Leeds University
1995 Appointed Honorary Visiting Professor in Department of Biology, York University

Key Training

1987 (April) Henley Management College - Senior Course
1993 (January) Institute of Management - The Leaders Seminar
1995 (summer) Whitehall & Industry Group Business Attachment Scheme placement with Marks and Spencers Ltd
1999 (June) Cabinet Office Trevelyan Programme (Modernising Government)

Membership of Professional Organisations

Environmental Panel of the UK Advisory Committee on Pesticides (Chairman 1986 – 1996)
Expert Member and Chairman of EU Scientific Committee on Plants (1997-2003).
Expert Member of EU Scientific Steering Committee (1998-2003).
Expert Member and Chairman of EFSA Plant health, Plant protection products and their Residues (PPR) Panel (2003-2006)
Expert Member of EFSA Scientific Committee (2003-2006)
Expert Member and Chairman of EFSA Plant protection Products and their Residues Panel (2006 – 2009)
Expert Member of EFSA Scientific Committee (2006 – 2009)
Expert Member and Chairman of EFSA Plant protection Products and their Residues Panel (2009 – 2012)
Expert Member of EFSA Scientific Committee (2009-2012)
Expert Member and Chair of EFSA Scientific Committee (2012-2015)
Expert Member and Chair of EFSA Scientific Committee (2015-2018)

Chairman of Venturefest Yorkshire (2009-2015) (www.venturefestyorkshire.net)

British Ecological Society
British Ornithologists Union
British Trust for Ornithology (former Council member)
Association for the Study of Animal Behaviour
Mammal Society
Society for Ecotoxicology and Chemistry

Languages

French - limited oral and written ability, Italian – limited oral and reading

IT

Competent user of Microsoft Office, Microsoft Word, Microsoft Exel , Microsoft Powerpoint and the internet.

Additional Personal Details

Date of birth: 6 May 1951
Interests: Hill walking, cycling, natural history, bird watching, music, photography, reading, watercolour painting, genealogy.

Publications

Hirons G, **Hardy A** and Stanley P. (1979). Starvation in young Tawny Owls. *Bird Study* **26:** 59-63.

Hardy A R and Minton C D T. (1980). Dunlin migration in Britain and Ireland. *Bird Study* **27:** 81-92.

Hardy A R, Hirons G and Stanley P I (1981). The relationship of body weight, fat deposit and moult to the reproductive cycles in wild Tawny Owls and Barn Owls. In*: Recent Advances in the study of raptor diseases*. pp 159-163. Cooper J E and Greenwood A G (Eds). Chirons Publications Ltd., Keighley.

Hardy A R, Hirons G, Stanley P I and Huson L W (1981). Sexual dimorphism in size of Tawny Owls (*Strix aluco*): a method for sexing in field studies. *Ardea* **69**: 181-184.

Hardy A R, Quy R J and Huson L W (1983). Estimation of age in the Norway rat (*Rattus norvegicus* Berkhout) from the weight of the eyelens. *Journal of Applied Ecology* **20**: 97-102.

Stanley P I and **Hardy A R** (1983). Methods of prediction of environmental effects of pesticides. Field trials to assess the hazard presented by pesticides to terrestrial wildlife. In: *Proc.Int.Cong. Plant Protection, 10th, Brighton 1983*, **2**: 692-701. British Crop Protection Council, Croydon.

Westlake G E and **Hardy A R** (1983). Effects of storage and pesticide treatments on honey bee brain acetyl cholinesterase activities. In: *Proc. Int. Cong. Plant Protection, 10th, Brighton 1983*, **2**: 715. British Crop Protection Council, Croydon.

Fletcher M R and **Hardy A R** (1983). Pesticides and wildlife - a review of wildlife incidents investigated from October 1981 to September 1982. In: *MAFF/ADAS Agricultural Science Service Research and Development Report Pesticide Science 1982*, Reference Book 252(82), pp 47-55.

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 Symnposium No. 13, Institute of Terrestrial Ecology, Cambridge.

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.

Hirons G J M, **Hardy A R** and Stanley P I (1984). Body weight, gonad development and moult in the Tawny Owl (*Strix aluco*). *J.Zool. Lond.* **202**: 145-164.

Fletcher M R and **Hardy A R** (1984). Pesticides and wildlife - a review of wildlife incidents investigated from October 1982 to September 1983. In: *MAFF/ADAS Agricultural Science Service, Research and Development Report Pesticide Science 1983*, Reference Book 252(83), pp 39-47.

Westlake G E, **Hardy A R** and Stevenson J E (1985). Effects of storage and pesticide treatments on honey bee brain acetyl cholinsterase activities. *Bull. Environ. Contam. Toxicol.* **34**: 668-675.

Fletcher M R and **Hardy A R** (1986). The impact of pesticides on wildlife: A review of wildlife incidents investigated from October 1983 to September 1984. In: *Research and Development Report: Agricultural Science Service 1984.* Reference Book of the Ministry of Agriculture, Fisheries and Food, London, No. 257(84), pp 72-80.

Hardy A R (1986). Boxworth examines wildlife spray patterns. Farmers Weekly, August 29, 1986.

Hardy A R (1986). The Boxworth Project - a progress report. In: *1986 British Crop Protection Conference - Pests and Diseases,* 1215-1224. British Crop Protection Council, Croydon.

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.

Fletcher M R and **Hardy A R** (1987). The impact of pesticides on wildlife: a review of the wildlife incidents investigated from October 1984 to September 1985. In: *Research and Development Report: Agricultural Science Service 1985.* Reference Book of the Ministry of Agriculture, Fisheries and Food, London, No. 257(85), pp 58-65.

Mackness M I, Thompson H M, **Hardy A R** and Walker C H (1987). Distinction between 'A' -esterases and arylesterases - implications of esterase classifications. *Biochem.J*. **245**: 293-296.

Hardy A R (1987). Ecotoxicology of pesticides: the laboratory and field evaluation of the environmental hazard presented by new pesticides. In: *Toxicology of Pesticides: Experimental, Clinical and Regulatory Aspects.* Costa, L G *et al* (Eds). Springer-Verlag, Berlin, Heidelberg, pp 185-196.

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Thompson H M, Walker C H and **Hardy A R** (1988). Esterases as indicators of avian exposure to insecticides. In: BPC Monograph 40*, Field Methods for the Study of Environmental Effects of Pesticides*. (Eds). Greaves M P, Smith B D and Greig-Smith P W. pp 39-45. British Crop Protection Council, Thornton Heath.

Cowan D P, **Hardy A R**, Vaughan J A and Christer W J (1989). Rabbit ranging behaviour and its implications for the management of rabbit populations. In: *Mammals as Pests* (Ed). Putman R, pp 178-185. Chapman & Hall, London.

Hardy A R (1989). The dilemma - when and when not to kill? The role of control in vertebrate pest management. In: *Killing with Kindness*. Proceedings of British Veterinary Association Symposium, November 1988.

Hardy A R (1990). Estimating exposure: the identification of species at risk and routes of exposure. In: Somerville L and Walker C H (Eds) *Pesticide Effects on Terrestrial Wildlife*, pp 81-97 Taylor & Francis, London.

Thompson H M, Walker C H and **Hardy A R** (1990). The use of avian serum 'B' esterases in monitoring exposure to organosphosphorus insecticides. In: Somerville L and Walker C H (Eds) *Pesticide Effects on Terrestrial Wildlife* pp 348-349 Taylor & Francis, London.

Hardy A R and Inglis I R (1990). Wildlife as bio-indicators. In: *Transactions of the 19th Congress of the International Union of Game Biologists (IUGB)*, Trondheim, Norway, September 1989.

Hardy A R (1990). Trap legislation, testing and approval in the United Kingdom. In: *Proceedings of International Symposium on Trapping Wild Furbearers*, Edmonton, Canada, November 1988.

Hardy A R (1990). Vertebrate pests of agriculture. Present problems and future solutions. In: *Proceedings of 14th Vertebrate Pest Conference*, Davis L and March R E (Eds), University of California, Davis, pp 181-185.

Thompson H M, Walker C H and **Hardy A R** (1991). Inhibition of avian esterases by organophosphorus insecticides; problems of reactivation and storage. *Arch. Environ. Contam. Toxicol.* **20**: 509-513.

Thompson H M, Walker C H and **Hardy A R** (1991). Changes in activity in avian serum esterases following exposure to organosphosphorus insecticides. *Arch. Environ. Contam. Toxicol.* **20**: 514-518.

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Hardy A R (2007). How safe is our food? Whom do you trust? (Keynote paper). *Proceedings of XVI International Plant Protection Congress 2007 (Glasgow 15-18 October, 2007)* Vol.**1**: pp 8-19.

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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**. Development of a framework based on an ecosystem services approach for deriving specific protection goals for environmental risk assessment of pesticides (2011). *Science of the Total Environment* **415**: 31-38

J-LCM Dorne, D Benford, A Ragas, L Posthuma, GE Kass, P Manini, B Dujardin, E Benfenati, **A Hardy**, E Testai, L Castle, C Svendsen, S Bennekou, R Laskowski, R Solecki, JC Leblanc, A Kortenkamp, P Kille, P Price, T Backhaus, N Cedergreen, C Hogstrand. Harmonised risk assessment for human health and ecological risk assessment of combined exposure to multiple chemicals: a food and feed safety perspective (2018). *Toxicology Letters* 295:S37-38 https://doi.org/10.1016/j.toxlet.2018.06.1155

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Joint author of 256 internet published opinions :

EU Scientific Committee on Plants (SCP) and EU Scientific Steering Committee (SSC) 149 opinions (1997-2003):

- SCP GMO opinions (http://ec.europa.eu/food/fs/sc/scp/outcome_gmo.en.html)
- SCP Pesticides opinions (http://ec.europa.eu/food/fs/sc/scp/outcome_ppp.en.html)
- SSC opinions (http://ec.europa.eu/food/fs/sc/ssc/index_en.html)

EFSA Plant Protection Products and their Residues (PPR) Panel and EFSA Scientific Committee (SC) 107 opinions (2003-2019)

- PPR opinions (http://www.efsa.eu.int/EFSA/ScientificPanels/PPR/efsa_locale-1178620753812_Opinions475.htm)
- SC opinions (http://www.efsa.eu.int/EFSA/ScientificPanels/efsa_locale-1178620753812_ScientificCommittee.htm)
- The EFSA Journal is now published by Wiley http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1831-4732

PERSONAL INFORMATION

Sari Päivikki Autio

Finnish Safety and Chemicals Agency Tukes, PO Box 66, 00521 Helsinki, Finland
Home: Etelärinteentie 44, 10300 Karjaa, Finland

+358 29 5052196 +358 50 409 6379, personal mobile: +358 50 539 4044

sari.autio@tukes.fi

www.tukes.fi

ORCiD 0000-0002-4169-7268

Sex Female | Date of birth 31/08/1961 | Nationality Finnish

POSITION

Senior Officer, Finnish Safety and Chemicals Agency Tukes

WORK EXPERIENCE

1.1.2021 – currently

Finnish Safety and Chemicals Agency Tukes, Helsinki, Finland

Senior Officer

I am responsible for international affairs concerning the safety, authorisation, control, and surveillance of chemicals, particularly plant protection products. Representing Finland in the EU SCoPAFF, Steering committee on chemical authorities (NKE) under the Nordic Council of Ministers, EU DG SANTE working groups on the sustainable use of pesticides and specific protection goals for ecotoxicology.

My work is focusing on the risk mitigation and reduction of uses and risks of plant protection products, alternative and non-chemical plant protection methods, low risk and biological products. Assessment and planning of the activities of the National Action Plan on the sustainable use of plant protection products, including the coordination of its task forces on organic/IPM and monitoring of residues in the environment.

Participation in expert groups and projects:

- Tutor in the European BTSF training programme on the risk assessment of microbial plant protection organisms (RAMO) 2021-2023.
- Member of the expert committee of the INRAE (FR) led project “Pathways towards chemical pesticide free agriculture in Europe in 2050”.
- Member of the Expert Group for Technical Advice on Organic Production (EGTOP) of the EU DG AGRI, chairing its sub-group on cleaning agents and disinfection, and member of the sub-group on fertilisers and plant protection products (2022-2025).
- Secretary of the consultative sub-committee for EU affairs on plant protection products under the Ministry of Agriculture and Forestry.
- In 2013 and repeatedly in 2018, member of an international visitation committee for evaluating the scientific process, scientific output and decision-making process of the Netherlands Board for the Authorization of Plant Protection Products and Biocides (Ctgb). In particular, I focused on the processes of risk assessment and authorization of biopesticides in the 2018 evaluation.

Business or sector Governmental Authority

1.6.2017 - 31.12.2020

Natural Resources Institute Finland (Luke), Helsinki, Finland

Research Manager, Finnish Organic Research Institute (FORI), temporary contract on the leave of absence from Tukes.

Coordination of the multidisciplinary network of researchers on organics at the Luke and the University of Helsinki. Finnish Organic Research Institute (FORI) operates under the University of Helsinki and the Natural Resources Institute Finland (Luke) and promotes organic food production and consumption throughout the Finnish food chain by the means of research, science communication, education, and development projects.

Representative of Luke in the research initiative “Towards Chemical Pesticide Free Agriculture”. Member in the consultative EU sub-committee for organic food and farming under the Ministry of Agriculture and Forestry. Participation in projects Luomubuumi (2018-2021), KILPA 2020 (2018-2021), SoildiverAgro (2019-2021) in Luke, as well as in steering committees of several other research projects. Supervising and examining of theses on organics for the University of Helsinki, faculty of agriculture and forestry. Organisation of seminars, lectures, workshops and stakeholder events and communication about the scientific research on organics to professionals and the society in general.

Business or sector Research

1.1.2011 - 31.5.2017

Finnish Safety and Chemicals Agency (Tukes), Plant Protection Products Unit, Helsinki, Finland

Senior Adviser

30 years of experience in environmental fate and ecotoxicological risk assessments of plant protection products both at national and international levels. EU risk assessments of active substances for which Finland is the Rapporteur Member State and defending the evaluations of those active substances at the EFSA peer review. international cooperation in the decision making within the DG SANTE SCoPAFF, 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 Council of Ministers and in the EU Northern Zonal Steering Committee. Coordination of the update of the Guidance Document on work-sharing in the Northern zone in the registration of plant protection products, which is a living document to be updated according to progressing science and the development of EU guidances.

I also participated in the preparation of the National Action Plan (NAP) on the sustainable use of Plant Protection Products in Finland, and the steering committee of its implementation. Consequently, the motivation for my doctoral studies grew from the experience on preparing and implementing the Finnish NAP, and Tukes granted me two years study leave in 2014-2015. The topic of my PhD thesis is: “Do we listen to earthworms? Tools for evaluating the Finnish National Action Plan on the sustainable use of plant protection products”.

Business or sector Governmental authority

1.9.1990 - 31.12.2010

Finnish Environment Institute (Syke), Chemicals Division, Helsinki, Finland

Senior Adviser

- Environmental risk assessment of plant protection products (environmental fate and ecotoxicology), about the tasks, please see above.
- I have about five years of experience on leading the PPP-team in Syke, and two years of experience as project coordinator within the Pilot project on Biocides funded by the Commission DG ENV.
- During the preparation of the EU legislation on plant protection products, I supported the Finnish delegation of the Council working group (2006-2009).
- The change of employer was due to re-organisation of the chemical safety authorities in Finland. I was closely involved in the planning of the legislative transition and re-organisation.

Business or sector Governmental authority

1.7.1988 – 31.8.1990

Ministry of the Environment, Helsinki, Finland
Researcher

- Environmental risk assessment of plant protection products (environmental fate and ecotoxicology), about the tasks, please see above.
- The chemical risk assessment tasks were based on temporary contracts.

Business or sector Governmental authority

1985 – 1988

University of Helsinki, Department of Environmental Science, Helsinki, Finland

Researcher (variable periods, temporary contracts)

- Ecotoxicological research on hazardous substances and heavy metals in the environment
- Mobility and leaching of heavy metals in Finnish soils

Business or sector Research

EDUCATION AND TRAINING

12/2013 – 3/2017

PhD in Environmental Science

University of Helsinki, Faculty of Biological and Environmental Sciences,
Department of Environmental Sciences, Helsinki, Finland

- PhD thesis "Do we listen to earthworms? Tools for evaluating the Finnish National Action Plan on the sustainable use of plant protection products"

09/1981 – 04/1988

MSc in Environmental Science

University of Helsinki, Faculty of Agriculture and Forestry, Institute of Environmental Science, Helsinki, Finland

- MSc thesis about heavy metal contents in mushrooms in acidified and non-acidified forests

PERSONAL SKILLS

Mother tongue: Finnish

Other languages

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
Swedish (2nd official language in Finland)	C2	C2	C2	C2	C2
English	C2	C2	C2	C2	C2
German	B2	B2	B1	B1	B2
Russian	A2	A2	A2	A2	A2
Estonian	A2	B1	A2	A2	A2

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user
Common European Framework of Reference for Languages

Communication skills

Good communication skills gained through my experience in coordinating the organic/IPM taskforce of the NAP and the network of researchers at FORI and communicating the research on organics to the general public. Fluent writer and speaker both in popular and scientific contexts.

Organisational / managerial skills

- Leadership and coordination of the expert group on the NAP (ca. 70 experts representing research, authorities, agricultural advice, education, professional users, sales and retailers of plant protection products, NGOs)
- Leadership and coordination of the multidisciplinary network of researchers of the FORI (ca. 160 researchers at Luke and the University of Helsinki)
- Steering committee member to supervise research projects on the sustainable use of PPPs, on the organic food and farming, as well as on environmental impacts of plant protection products
- Steering committee member of projects contributing to chemical safety and development of risk assessment methodologies, funded by the Nordic Council of Ministers
- Project management skills gained in many projects during my career
- Good knowledge on the organisation and responsibilities of the competent authorities on chemicals
- Leadership and coordination of the environmental risk assessment team of plant protection products

Job-related skills

- Good knowledge on the organic food and farming, especially on the environmental impacts
- National editor for Organic Eprints (http://orgprints.org/) in 2017-2020
- Extensive experience on the risk assessment procedures, methodologies and decision-making on approval and authorisation of pesticides in the EU
- Good knowledge and experience on the National Action Plans on the sustainable use of pesticides in the EU
- Experience and skills of interdisciplinary research
- Experience on international research networking on organics, e.g., IFOAM-EU and TP Organics
- Good teaching skills: supervising undergraduate students in master's studies, evaluating the theses, and lecturing at the courses on organic food and farming upon the request of the University of Helsinki.
- International course on university pedagogics Autumn 2015, University of Helsinki.
- International course on Multiple Criteria Decision Analysis Spring 2017, University of Helsinki.

Digital skills

SELF-ASSESSMENT				
Information processing	Communication	Content creation	Safety	Problem solving
Proficient user	Proficient user	Basic user	Independent user	Basic user

Levels: Basic user - Independent user - Proficient user
Digital competences - Self-assessment grid

HAUS eOppiva certificate of completion, ABC of data protection for public administration, 16.12.2019

Computer skills:

- good command of Microsoft Office programs (Word, Excel, PowerPoint, Outlook, OneNote)
- experience in EU FOCUS models and scenarios for ground water and surface water risk assessment of plant protection products
- Interest in environmental risk indicators of chemicals, e.g., the HAIR 2010

Other skills

Interest in evaluation research:

- In 2022, Evaluation of the Finnish National Action Plan for the sustainable use of plant protection products II (2018-2022)
- In 2019-20, contribution of FORI to the external evaluation of Luke.
- In 2013 and 2018, I was invited to a five-member international visitation committee for evaluating the scientific process, scientific output and decision-making process of the Netherlands Board for the Authorisation of Plant Protection Products and Biocides (CTGB).
- In 2017, Tukes conducted an internal evaluation of its risk assessment processes of plant protection products and biocides, for which I contributed on the basis of the Dutch experience.
- In 2016, my PhD research contributed to the methodologies of evaluation of the Finnish National Action Plan for the sustainable use of plant protection products.

Driving licence AB

ADDITIONAL INFORMATION

Memberships

Expert Group for Technical Advice on Organic Production (EGTOP), EU DG AGRI (2022-2025)
Sub-committee of the EU issues on plant protection products under the Ministry of Agriculture and Forestry, Finland (secretary)
Sub-committee of the EU issues on organic farming under the Ministry of Agriculture and Forestry, Finland (2018 - 2020)
International Visitation Committee for the Ctgb, NL (2013, 2018)
Steering group of the InnoFood research programme at Luke (2017 - 2020)
Steering group for the Finnish National Action Plan on the sustainable use of plant protection products (2011-)
Finnish Society of Environmental Sciences
Council Member of the Trade union for natural, environmental and forestry scientists Loimu (2017 –)
Steering group member in research projects concerning the environmental effects of plant protection products and organic food and farming
OECD expert group on pesticide risk indicators (EGPRI) (2011 -2016)
Kevake working group for re-organizing the chemicals product surveillance tasks from three separate authorities to Finnish Safety and Chemicals Agency Tukes (2010). The new organization started in 2011.

Honours and awards

SL R Knight of the Order of the Lion of Finland 6.12.2009

Projects

Luoto 2019 (The activities of FORI) 2019-2020
Kilpa 2020 (The environmental performance of Finnish animal production) 2018-2020
Luomubuumi (More organics onto the market by increasing the knowledge of producers) 2019-2021
SoildiverAgro (Diversity of soil organisms in organic farming) 2019-2023

Selected publications in English

Autio, S., Laitala, E. & Kallio-Mannila, K. 2022. Evaluation of the Finnish Action Plan for the Sustainable Use of Pesticides. Manuscript submitted to Agricultural and Food Science

Autio, S. 2021. "Assessing Assessors – How to Evaluate the Scientific Performance of a Pesticide Regulatory Authority", published on *REALaw.blog on 22.10.2021* and available at: https://realaw.blog/?p=610

Autio, S., Koëter, H., Carretero, M., Hardy, A.& Mantovani, A. 2021. Assessing assessors: proposal for a guidance for evaluating the scientific performance of a pesticide regulatory authority. European Journal of Risk Regulation, 1–13. doi:10.1017/err.2021.11

Autio, S. & Iivonen, S. 2021. Research data and solutions for the development of organic production in Finland – Finnish Organic Research Institute's research strategy for 2021–2024. Research data and solutions for the development of organic production in Finland – Finnish Organic Research Institute's research strategy for 2021–2024 (luomuinstituutti.fi)

Peltoniemi, K., Talgre, L., Autio, S. & Känkänen, H. 2020. Chapter 10. Improving soil quality with cover crops. Pp. 124-139 in: Soto-Gómez, D., Shanskiy, M. & Fernández-Calviño, D. (eds.) 2020. Interactions between agricultural management and soil biodiversity: An overview of current knowledge. E-book deliverable of WP 2 of the SoildiverAgro project financed by the EU Horizon2020 research and innovation programme under grant agreement No. 817819. http://soildiveragro.webs5.uvigo.es/wp-content/uploads/2020/12/Ebook-WP2-Interactions.pdf

Iivonen, S. & Autio, S. 2019. Environmental impacts of organic farming. P. 88-90 in: Niemi, J. & Väre, M. (eds.) Agriculture and food sector in Finland 2019. Natural resources and bioeconomy studies 37/2019. Natural Resources Institute Finland (Luke), Helsinki.

Koëter, H., Autio, S., Carretero, M., Hardy, T. & Mantovani, A. 2018. Report of the second 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. 09/2018.

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

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.

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

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 of the Finnish Research Programme on Environmental Health – SYTTY 1/2000. P. 113-118.

europass

Europass Curriculum Vitae

Personal information	
Surname(s) / First name(s)	**Mičović Elizabeta**
Address(es)	Kašeljska cesta 134, 1260 Ljubljana -Polje, Slovenija
Telephone(s)	(+386) 1 580 76 46 / Mobile: (+386) 30 721 100
E-mail	elizabeta.micovic@guest.um.si / elizabeta.micovic@gmail.com/ elizabeta.micovic@gov.si
Nationality	Slovenian
Date of birth	09.09.1960
Gender	Female
Occupational field	**Food technology, Management in Food industry, Government Councelling, Food safety, public health, Consumer protection, Risk management, Risk communication, Public Relations**
Work experience	
	April 1984 → June 1998:
	· Quality monitoring of raw materials, packaging materials and food products; · Development of confectionary products (muesli bars, crunchy muesli, bakery products, dessert toppings, extruded products); · Production of technology documentation (recepies, instructions, product specifications, labels); · Implementation of the Quality System ISO 9001 in the department of development and technology of confectionary; · Implementation of the HACCP system in food production of confectionary products.
Name and address of employer	**Mercator Emba, Slovenčeva 21, Ljubljana, Slovenia**
Type of business or sector	Food industry. The main activity of the company are coffee processing, production of instant drinks and hot chocolate, toppings for ice cream, cereal products and packaging of dry fruits and nuts.
Occupation or position held	Technologist for Quality, Production and Development; Microbiologist
	July 1998 → October 2002:
Occupation or position held	- Technologist for Quality, - Production and Development, Head of the Development department and Technology of Confectionery, - Production Manager Assistant, - Head of HACCP team for confectionary production;
Main activities and responsibilities	- Development of confectionary products; - Head of the HACCP team, Implementation of HACCP in the production of confectionary;

Name and address of employer	**Žito Gorenjka, Rožna dolina 8, Lesce, Slovenia**
Type of business or sector	Food industry, production of bakery products, chocolate, and other confectionary products
	November 2002 → December 2004
Occupation or position held	Health Inspector, Deputy Director of the regional unit of Health Inspectorate of Republic of Slovenia Ljubljana, Project assistance and/or project management
Main activities and responsibilities	- Trainer of inspectors of ISO 9001; - Lecturer in nutrition (functional products, deveopmenta of new food product); - Participation in official control and audit of HACCP in several companies (retailors: Petrol, o OMV Isztrabenz, Mercator; food industry: Kolinska, Žito, Mercator Emba, Mercator o Eta, Pivovarna Union); - Monitoring of food safety, Sampling of different sort of food; managing of the recall system; - Participation in the Rapid Allert System of Food and Feed; - Implementation of the Resolution on the National Programme of Food and Nutrition Policy o 2005 – 2010; - Member of the working group for collaboration with food industry under the ministerial o Council for food and nutrition; - Head of Working Group for Food Hygiene; - Deputy of Director of Regional unit Ljubljana -
Name and address of employer	**The Health Inspectorate of the Republic of Slovenia, Parmova 33, 1000 Ljubljana**
	January 2005 → July 2006
Occupation or position held	Senior Adviser
Main activities and responsibilities	Advising on field of nutrition, Envorinmental impacts on health, Food safety
Name and address of employer	**The Ministry of Health, Directorate for Public Health,Štefanova 5, 1000 Ljubljana Slovenia**
Type of business or sector	Government
	July 2006 → april 2010
Occupation or position held	Undersecretary, Deputy Head Division for food safety
Main activities and responsibilities	- Work on field of Food safety (Pesticide residue, official control, food labeling, hygiene); Member - of the Consumer Protection Council under the Ministry of the Economy; - Participation in the Working Group for Foodstuffs at the Council of EU and European - Commission (Official control, Nutrition and Health claims, Labelling nutrition value, - General labelling); - Project leader of project named "Increasing networking and upgrading administrative capacity in - the management of food and feed safety in Slovenia financed by the European Commission", - Transition Fascility 2006 - 2007; - Project leader of project " Feasibility Study of the equipment financed by the European - Commission necessary for increasing and upgrading Feasibility administrative capacity - in the management of food and feed safety in Slovenia in year 2007;
Name and address of employer	**The Ministry of Health, Directorate for Public Health, Food Safety Divison, Štefanova 5, 1000 Ljubljana Slovenia**
	May 2010 →January 2013
Occupation or position held	Undersecretary, Coordinator for Food and Feed Safety in the Directorate for Food Safety, Deputy Head Division for Food and Feed Safety;

Name and address of employer	- Coordination of work on field of Food and Feed safety (Pesticide residue, Food labeling, GMO, Hygiene, Novel Food, Additives, Contaminants, Biological Safety, Official Control, Consumer Protection…). - Labelling nutrition value, General labeling, SCFCAH -Standing Comeetee on the Food Chain and Animal Health, Section: Food Law); - Coordination in risk managing team dealing with E. coli outbreak with aim to protect consumers' health; as health inspector I was dealing with poisoning of consumers with buckwheat; - *Extended Networking Meeting regarding project: FOCUS-food consumer science in the Balkans, Podgorica, Montenegro, 7June 2011* - Giving lectures in Training courses in Serbia in Ministry of Agriculture – Risc communication in food safety area (November, 2011; for Institut fur Europaishe Politik) - Participation in NATO Advanced Research Workshop on Managing Global Environmental Threats to Air, Water and Soil , Ljubljana, Slovenia, 28-30 June 2010; Understanding and managing threats to the environment in South Eastern Europe - Giving lectures regarding Nutrition and Health claims labeling (Regulation 1924/2006) for GO (Health Inspectorate, Veterinary Office, Inspectorat of Agriculture) and NGO (Institut Nutris, Chamber of Commerce, … - Participation in work shop WHO 'Capacity Building on Environment and Health' in Latviji, Riga 19-23, marec 2011; **The Ministry of Agriculture, Forestry and Food, Food Safety Directorate,**
	February 2013 → October 2016
Name and address of employer	- Responsible for food safety area: food labeling, health and nutrition claims, fortified food, novel food; - Participation in the Working Group for Foodstuffs at the Council of EU and European Commission (Nutrition and Health claims); - Member of SCFCAH -Standing Comeetee on the Food Chain and Animal Health, Section: Food Law; - Expert mission on Risk identification, risk assessment and determination of critical control points in the confectionery industry; in Podgorica Montenegro, 5-7/11/2012 **November 2016 →May 2019** Head of Public Relation Service at the Administration of Food safety, veterinary sector and plant protection, responsible for risk and crisis communication; - Preparing communication plans for campaigns on area of animal health and wellfare, plant health and and food safety; - Communication with public: (media, government organizations, nongovernment organizationa, universities… - Implementation of risk communication in case *of Aviar Influenza, polish meat, fire in industry,* **The Administration of the Republic of Slovenia for Food safety, Veterinary sector and Plant protection**

	June 2019 →May 2021 **Secretary at the Public Relation and Promotion Office, Directorate for Food, Promotion of Agriculture and Food Products Section** - Preparing communication plans for campaigns on area of animal health and wellfare, plant health and food safety; - Communication with public: (media, government organizations, nongovernment organization, universities…) - Preparing press releases, speeches for Minister; - Organising different events (celebrations of food safety day, food day and others…) - Preparing communication plans for different campaigns on area of agriculture and food products; - Head of project: preparing World Bee Award; - **Ministrstry for Agriculture, Forestry and Food** **June - 2021 →** Head of Communication and Public Relations Unit - Preparing communication plans for campaigns on area of Rural Developments (social media, web sites, media); - Communication with public: (media, government organizations, nongovernment organization, universities, farmers…) - Preparing press releases, speeches for Director General; - Organising different events; **Agency of the Republic of Slovenia for Agricultural Markets and Rural Development**
Education and training	
	2007 - 2010
Title of qualification awarded	Postgraduate study: PhD
Principal subjects/occupational skills covered	Food safety, Chemical Safety, Consumer Protection, Consumer Rights, Risk management, Invisible Threats; Doctoral thesyis: *''Recognising invisible victimization regarding food safety and consumer protection''*
Name and type of organisation providing education and training	University of Maribor, Faculty of Criminal Justice and Security Ljubljana:
Level in national or international classification	Doctoral studies
	1990 – 2003
Title of qualification awarded	Postgraduate study: M. Sc
Principal subjects/occupational skills covered	Food technology, Food Quality, Development of new food product;
Name and type of organisation providing education and training	University of Ljubljana, Food Science and Technology, Ljubljana, Slovenia Thesis title: *"Quality of functional product – chocolate with inulin"*
Level in national or international classification	Master of science in food technology (distinction: Excellent)
	1979 – 1984
Title of qualification awarded	Food technologist
Principle subject/occupational skills covered	Food Science and Technology, Nutrition, Food Quality, Food Safety Thesis title: *''Determination of genotoxicity of spices''*
Name and type of organization providing education and training	University of Ljubljana, Food Science and Technology, Ljubljana, Slovenia

Personal skills and competences			
Mother tongue(s)	**Slovenian**		
Other language(s)	**English, Serbian,Croatian, French language**		
Self-assessment	**Understanding**	**Speaking**	**Writing**
English	excelent	good	good
Serbian	exelent	excelent	good
Croatian	exelent	excelent	good
Slovenian	excelent	excelent	excelent
French	fair	fair	fair
Social skills and competences	• Teamwork: I have successfully worked in various types of national and international teams (food technology, development of new products, food safety, HACCP team, ISO 2001…) • Mediating skills: I work on the borders between consumers, food operators and risk managers. • Intercultural skills: I have experience as representative of RS in Working Groups of experts and Standing Committees in European Commission and Working Group in the Council. I was project leader of Transition Fascility projects and I coordinated Danish partner and both Ministries involved into the project: Ministry of Health and Ministry of Agriculture, Forestry and Food of Republic of Slovenia; • Welfare skills: Highly developed sense for human and animal welfare and environment protection, consumer rights; • Good communication skills including communication with NGO and public media.		
Organisational skills and competences	• Project leader skills; • Team management skills; • I have organised several working groups on national level on fielid of Nutrition Action plan in Slovenia; • From 2005 to 2010 I was the memeber of professional Council in Office of the Republic of Slovenia for Consumer Protection on Ministry of Economy; • Since 2006 to 2016 I was an expert of Working Group of nutrition and health claim in European Commission. • Since 2007 to 2010 I was an expert of Working Group of food labeling in Councill of Europe. • Since May 2010 to 2016 I was a member of STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH, Section: "General Food Law"; • Since 2013 to 2016 I was an expert of Working Group for novel food in European Commission		

Expert and speaker at TAIEX events	- Expert mission on Health and Nutritional claims in Zagreb, 24-27 November 2008; as expert (TAIEX); - Expert mission on Risk identification, risk assessment and determination of critical control points in the confectionery industry; in Podgorica Montenegro, 5-7/11/2012 - Multi country Workshop on Preventive Actions against Excessive Salt intake, 2013, Montenegro; - Workshop on official control and audit of the HACCP system in catering, 2014 Former Yugoslav Republic of Macedonia; - Workshop on Food Sampling and Official Controls (22- 24 October, 2014, Ankara); - Workshop on labelling, marketing and control of traditional food 01-02. December 2014 – Beirut, Lebanon) - Workshop on official controls concerning microbiological sampling and testing of foods, AGR 58604, 27- 28 April 2015, Prishtina - Expert Mission on consumers protection, AGR 58924, 18-19 May 2015, Skopje - Workshop on consumers protection, AGR 58923, 20-21 May 2015, Skopje - Workshop on dietary surveys, AGR 56041, 01- 02 June 2015, Belgrade - Workshop on Sustainable Food Safety Control Systems implementation in SMEs, AGR 54824, 13-14 July 2015, Beirut, Lebanon; - Workshop on Implementation of European Union legislation and European standards in food and agriculture sector, AGR 60418 14.15 December 2015, Chisinau - TAIEX RTP Workshop on Food Sampling and Official Controls: AGR 61247; 10-11. February in Ayvalik, Turkey; - TAIEX Expert Mission on Better Understanding of Food Information Regulations - AGR 61613, 26-28.April 2016 in Ankara; - TAIEX Workshop on pesticide residua in food AGR 63162; 10-11 May 2017 in Tunis, Tunisia - TAIEX Workshop on Traceability of Food and Feed AGR 64034: 12 February 2018, Tirana Albania. - TAIEX Expert Mission on Market Surveillance for Consumer Protection AGR 65474; 2-3 May 2018, Giza, Egypt; - *TAIEX Expert Mission on Residues, Toxins, Radionuclides and other contaminants of food, 1-2. October 2018, Kosovo;* - *TAIEX Workshop on EU Consumer (Rights) Law and Alternative Solutions on Settlement Consumer Disputes, Ankara, 8-9. November 2018*
Tutor at Better Training for Safer Food (BTSF)	- Key speaker for BTSF- better training for safer food on Project: HACCP principles and audit techniques (April 2014 – October 2015) - Key speaker for BTSF- better training for safer food on Project: HACCP principles and audit techniques (April 2016 – October 2017) - Key speaker for BTSF- better training for safer food on Project: HACCP principles and audit techniques (September 2018 – January 2020); - Key speaker for BTSF training on: Auditing general hygiene requirements and control procedures based on the HACCP principles developed by food business operators Virtual Classroom (20021 -2022 in progress); Key speaker for BTSF Training course on Risk Assessment Course 8: Evidence collection, management and integration (Risc communication) in November and December 2022;
Computer skills and competences	Competent with MS Windows, MS Office (Word, Excel, Powerpoint, Outlook), Lotus Notes
Other skills and competences	Cooking Good in different sports: karate, nordic walking,
Driving licence	B

Annex	My advantages are experiences in area of Public Health, Nutrition, Food Safety, Consumer Protection and Risk Communication in different positions: - as technologist in food industry (implementation and using of food legislation, preparing documentation and ensuring safe and quality of food products); - as health inspector (official control regarding correct implementation of legislation); - as public servant at Ministry of Health - Directorate for Public Health, and at Ministry of Agriculture, Forestry and Food - Directorate for Food Safety (implementation of EU legislation at national level, preparing guidelines and recommendations for food operators and consumers; - 39 years of postgraduate progressively responsible professional experience in nutrition, public health, consumer protection, international development, emergency assistance and/or operational aspects of national, bilateral or multilateral food assistance, with a strong preference to work in food safety and development nutrition programs, with aim to protect consumers; - Experience in planning and/or managing nutrition programs including treatment as well as prevention and micronutrient programs (Member of the Working group for cooperation with industry (preparation of the Resolution on the National Program of Food and Nutrition Policy 2005-2010; member of the Consumer Protection Council under the Ministry of the Economy; participation in preparation of National Program for Consumer protection as representative of Ministry of Health RS; - Experience with programming of food assistance in emergency: coordination in risk managing team dealing with E.coli outbreak with aim to protect consumers' health; as health inspector I was dealing with poisoning of consumers with buckwheat; - Expirience in Public Relation Service (Head of Service) at the Administration for Food Safety, Forestry and Food and Agency of the Republic of Slovenia for Agricultural Markets and Rural Development
	Experience with policy and advocacy at different levels: Implementation of the Resolution on the National Program of Food and Nutrition Policy 2005-2010; - Leader of the Working Group for the nutrition of people with special dietary requirements: Implementation of National Nutrition Policy Program 2005-2010; - Leader of the Working Group for monitoring pesticide residua in feed and food (implementation of the Regulation (EC) No.396/2005); - Experience with survey methodologies, nutrition assessment, and operation research and relevant data analysis; I am familiar with all phases of risk analyses process (risk assessment, risk management and risk communication); during my education I used different methodologies (chemical analysis, sensory analysis, statistical methods-SPSS, Mann-Whitney U test and case-control study , 3-day weighing method…); As public servant I have many experiences in field of ensuring safe food, consumers' rights - I cooperate with Ministry of Health, association of Consumer Protection, Ministry of Economy, Institute for Public Health and others; - I am familiar with the latest developments/issues in nutrition, particularly in relation to food safety and nutrition, labeling of food, micronutrients, ensuring safe food and consumer protection against frauds and misleading, risk communication process; - Preparing Protocol for risk communication on field of ensuring food and feed safety in RS - Experience in public relations and communication with a different media (TV, radio, newspapers, interviews)

CURRICULUM VITAE

Personal data

Family name/christian name	**Mantovani Alberto** (M)
Adress (home)	via Giorgio Baglivi, 8 00161 Roma (RM)
(job)	Istituto Superiore di Sanità (ISS), viale Regina Elena, 299 – 00161 Roma
Phone	(+39) 06 4990 2815 (ISS)
	(+39) 333 7619642 (mobile)
Fax	(+39) 06 4990 2363
E-mail	alberto.mantovani@iss.it
Citizenship	Italian
Date of birth	February 22 1956
Marital status	Married
Professional Role	**Research Director - Istituto Superiore di Sanità**

EDUCATION AND TRAINING

1) Degree in Veterinary medicine at University of Bologna, Novembre 1979 (Dissertation "Risk assessment of anabolic agents in cattle production")
2) Master of Science in *Veterinary Public Health* - University of Edinburgh, UK-Scotland, October 1982 (disseration "Pesticide residues in foods of animal origin in Italy")
3) Period of study and training on in vitro methods of reproductiveand developmental toxicology at the Institut fur Toxikologie und Embryopharmakologie - Frei Universitat, Berlin (tutor: prof. Dieter Neubert, co-tutor: Dr. Stephen Klug) (October 1988-March 1989)

3) OECD courses on Good Laboratory Practice (GLP)

a) Rennes (France) (April 1989)

b) Gardone Riviera (BS) (April 1999)

Permanent education and training

- *as EFSA scoientific expert on risk assessment* (intensive events lasting 1-3 days)

4) Scientific Colloquium N°1: Methodologies and principles for setting tolerable intake levels for dioxins, furans and dioxin-like PCB's" (Bruxelles, June 2004)
5) Scientific Colloquium N°6: Risk-Benefit Analysis of Foods: Methods and approaches (EFSA, July, 2006)
6) Media training for panel members/PPR Team (EFSA, March 2014)
7) Specialised training "Evidence base for risk assessment" (EFSA, February, 2015)
8) Systematic Review Training - full process (EFSA, March 2015)
9) Adverse Outcome Pathway training course (EFSA, November 2015)
10) Uncertainty & Variability training course (EFSA, April 2016)
11) Scientific Colloquium N°22 'Epigenetics and Risk Assessment: Where do we stand?' (Valencia- Spagna, June 2016)
12) Chairing skills for Working Groups Chairs (EFSA, September 2016)
13) BenchMark Dose Modelling Training (EFSA, October 2016)
14) Critical appraisal of different individual study designs (EFSA, March 2017)
15) Training on Information retrieval techniques and search strategy design (EFSA, December 2018)
16) Critical Appraisal of Evidence (EFSA April 2019)

- *Other events relevant to permament education and training*

17) Eu-ToxRisk - Training course on Adverse Outcome Pathways (Leiden -NL, October 2017)
18) Training Course on the Application of the "EFSA/ECHA Guidance to identify Endocrine Disruptors (organized by Better Trainning for Safer Food on behalf of DG SANTE, ECHA and EFSA) (Bruxelles, February 2019)

Other languages (written and spoken)

English level: excellent

French level: good

DESCRIPTION OF MY PROFESSIONAL EXPERIENCE

2017 (March) – to date (October 2021)
Research director- Unit "Food, nutrition and health" - Department Food safety, Nutrition and Veterinary public health (italian acronym: SANV)- Istituto Superiore di Sanità (ISS)

Main activities and roles

Since March 2017, I work in the new Unit "Food, Nutrition and Health" which combines toxicological and nutritional skills. The organization of the new Unit takes place within the framework of the general reorganization of the ISS, which led to the formation of the SANV Department and the integration between previously existing structures.
My current mission in the Unit is to contribute to the scientific developments of *toxicological risk and risk-benefit assessmen*t, as well as to the scientific basis of the regulation of *endocrine disruptors*.
Furthermore, I work alongside the Director of the Department on scientific and organizational developments of a modern and broader vision of *One Health*, with particular attention toward the inclusion of *environmental* aspects, in collaboration with the colleagues from the Environment and Health Department.
The main outcomes of this 3-year period of activity include:

- strengthening the participation of the SANV Dept. - and of ISS - in the European research framework. To date (October 2021) I am the ISS Principal Investigator in the following projects:

(a) *EuToxRisk*, on the the development of the innovative approach to risk assessment pivoting on Adverse Outcome Pathways; (b) *SeaFoodTomorrow* (where I coordinate the task 3.1 "Technological Platform") on the the improvement of the benefit-to-risk relationship for aquacultura and fisheries; (c) *European Joint Programme on Rare Diseases*, where I coordinate the WorkForce "*Environment*" on the pathogenesis of birth defects with environmental risk factors; (d) *One Health European Joint Programme* (OHEJP) where I coordinate theWorkpackage 7 "*Sustainability*".
Within the frame of OHEJP, I recently co-organized and co-chaired the international Summer School "*Environmental issues in One Health: from risk assessment to surveillance*", hald (as virtual event) on 26/7-6/8/2021 and, as member of the Scientific and Local Organizing Committees, the OHEJP *Annual Scientific Meeting* (Orvieto-IT, April 2022).

The current activities in the field of *risk assessment* include

in the *international* context:

- the continuation of the activity as a scientific expert in support of the Competent Activity for the regulation of chemicals in the areas of the *REACH Regulation and the EU Regulation on Biocides*, with particular - but not exclusive – regard to the identification of endocrine disruptors
- the continuation of the activity as scientific expert of the E*uropean Food Safety Authority* (EFSA) in the FEEDAP Panel (safety for animals, humans and the environment of substances used in feed). I was a member of the Panel (until June 2018) and *chair of the Working Groups* Nutritional Additives and Other Additives. Since July 2018, having exceeded the maximum term of stay in the FEEDAP Panel according to the new EFSA rules, I continued my activity as an expert in the Nutritional Additives, Other Additives and Toxicology working groups
- the continuation of the activity as an Italian expert at the *OECD* in the *Endocrine Disruptor Testing and Assessment Working Grou*p on the criteria and methods for the identification and evaluation of endocrine disruptors
- a member of the International Visitation Committee in charge of reviewing the evaluation activity on *pesticides and biocides* of the Dutch authority (CTGB).
- Contribution to international training activities include:

a) EFSA events: a.1) Chair of the Satellite Workshop "Accounting for uncertainty in data-poor scenarios: Cases studies on risk analysis in food safety" at the *Joint EFSA/BfR International Conference on Uncertainty in Risk Analysis* (Berlin, February 2019); a.2) lectures "Setting the scene: Introduction to food safety and risk assessment" and "Concluding remarks" at Parma Summer School 2019 "*Risk-Benefit in Food Safety and Nutrition*" (June 2019); Lectures and training sessions on exposure assessment and toxicological studies at the "*EFSA training course on Risk Assessment of Feed Additives*" (December 2019); a.4) lecture "One Health – Environment & Health" at Parma Summer School 2020 '*One Health*' (June 2020); a.5) co-chair of the Workshop 2 - "Chemical Mixtures" at Parma Summer School on "*Food Safety Aspects of Integrated Food Systems*"(September 2021); a.5) lecture "Future challenges and perspectives of One Health in food safety" at EFSA *ONE-Health Regional Workshop for East ENP countries (*December 2021)
b) European Commission TAIEX programme: a..1) Expert Mission on *Residues, Toxins, Radionuclides and other contaminants of food* (lectures: "Hazard identification and management regarding rresidues, toxins, radionuclides and other contaminants of food"; "Introduction to risk management on radionuclides, metals and other organic pollutants of food"; "Management of toxic compounds of chemical origin") in collaboration with Food and Veterinary Agency of Kosovo (October 2018).; .2) Study Visit of the National Institute of Public Health of Albania on *Surveillance and Prevention of Congenital Malformations* (lecture: "Primary prevention strategies for congenital anomalies at Istituto Superiore di Sanità: Decalogue Food Safety and Nutrition in Pregnancy") (December 2018); a.3) Expert Mission on *Environmental and health risks of microplastics pollution*" (lectures: "Transfer of micro-plastics along the aquatic food chains and assessment of risks for human health"; "Toxicological evaluation of microplastics: health hazards for humans and ecosystems") in collaborarion with Albanian Institute of Public Health (May 2021); a.3.a) training of Albania experts on "One-health approach to microplastics risk assessment: an interactive workshop on food water" at the Study Visit on *Environmental and Health Risks of micro-plastic pollution* (November-December 2021)
c) FAO training programmes: lectures and training sessions on "Chemical Risk Assessment" at F*AO project on Strengthening food safety and animal health capacities in risk assessment and management in Armenia* (February 2020; February2021)
d) EU programme Better Training for Safer Food – BTSF: lectures and training sessions ("Interaction with non-target organisms and evaluation of exposure, potential risks, and effects";"Potential pathogenicity for humans and relevance of residues for human health") at the Course *Risk Assessment of Microorganisms used as Pesticides or Biocides* (seven courses till now: June-July 2021; October 2021 -2-courses-, November 2021, February 2022, June 2022).
e) One Health European Joint Programme (OHEJP): co-organizer and co-chair of the international Summer School "*Environmental issues in One Health: from risk assessment to surveillance*", (July-August 2021)
f) EU training programmes for Eastern Neighborhood Countries: lecture "Toxicological risk assessment as a component of the One Health approach" at Summer School "E*nvironmental Science Education for Sustainable Human Health*" within MEVINPRO "*Modernization of Environment Protection Studies Programmes for Armenia and Georgia*" (September 2021)
g) EU twinning project "*EU support to capacity building and gradual acquis alignment of the food safety sector in Bosnia-Herzegovina":* lectures and training sessions on "Revision of procedures in place and consultation on risk assessment of

impact of chronic and acute exposure to pesticide residues." nel Twinning project (June 2022)

In the *national* context:

- Contributions to the assessment and intervention in *areas and situations at risk* in this period
- *Landfill of Bussi sul Tirino*: publication (2017) of the results of the biomonitoring of persistent contaminants in indicator organisms as part of the PREVIENI Project, funded by the Ministry of the Environment
- Rapid assessment of toxicological risks related to the presence of *hydrocarbons in mineral water* (2018)
- Risk assessment of *trace elements in thermal waters* (2018-20)
- Contamination by *PFAS in Veneto*: (a) dietary exposure assessment and risk characterization produced by the SANV Department at the request of the Veneto Region (2019); (b) Member of the "Working Group on health aspects associated with pollution by perfluoroalkyl substances" of the Superior Health Council - Section III (2020)
- *Fire in the Aprilia waste depot:* member of the SANV - DAMSA Dept.working group on the assessment of the environmental impact on air and soil matrices and on the agri-food supply chains, and the consequent risks to human health (2020)

At the *Ministry of Health*:

– Member of the "*Technical Committee on the protection and promotion of health in the first 1000 days of life: from conception to two years of age*" set up at the Ministry of Health - Director of Prevention (appointment in 2016, document adopted by the the State-Regions Conference in February 2020)
- member for the third time of the *National Committee for Food Safety* (since October 2018) where I currently chair the Working Group "Mycotoxins;
– member of the permanent working group "*Mineral, thermal and spring waters*" at Section III of the Superior Health Council (appointment of the ISS Commissioner prot. 0009963 of 27/3/2019)

In the context of the *Covid-19 pandemic emergency*, although obviously not an expert in infectious diseases, I partucipated to

- Working group on the *professional use of ozone* also with reference to COVID-19,ISS COVID-19 Report 56/2020 (44 p.)

- *Policy brief: One Health-Based Conceptual Frameworks for Comprehensive and Coordinated Prevention and Preparedness Plans Addressing Global Health Threats* in support of the Task Force 1 "Global Health and COVID-19" T20 -G20 (September 2021) https://www.t20italy.org/2020/12/05/tf-1-global-health-and-covid-19/

- International crowdsourcing project *Modelling the pathogenesis of Covid-19 using the Adverse Outcome Pathway framework (CIAO)* co-ordinated by the EC Joint Research Centre (start July 2020, ongoing): working groups "Modifying Factors" e "Multiscale": https://ec.europa.eu/jrc/en/event/webinar/intro-webinar-ciao-project)

European Teratology Sociey (ETS, www.etsoc.com):

- president (2016-17): I organized the 45th Conference of the ETS (Budapest, September 2017) and Guest Editor of the special issue of *Reproductive Toxicology* dedicated to the event;

- past president (2017-18): I co-organized (with M. Beekhuizen) the ETS Education Course on *Adverse Outcome Pathways*.

Among my interventions in the international arena:

- Contribution to two events of the *European Parliament*:
a) Panelist al Joint Public Hearing PETI-ENVI "*Impact of Endocrine Disuptors on Public Health and the Environment*" (Bruxelles, March 2018);
(b) "Current and Emerging Toxicological Issues in Food Contact Materials" intervention at the Round Table at the European Parliament on *"Food Packaging and the Circular Economy: Making Health and the Environment a Priority*" organized by SAFE (Safe Food Advocacy Europe) (Bruxelles, April 2019)

- Scientific events:
- "Placenta as a target organ for EDCs: an AOP perspective". *9th Copenhagen Workshop on Endocrine Disrupters - COW2017*, (Copenaghen, May 2017)
- "Emerging issues in the assessment of endocrine disrupting chemicals", 5th International Bio-Medical Scientific Cyprus Congress (School of Medicine, European University Cyprus; Nicosia, November 2017)
- "Classification of developmental toxic pesticides and negligible exposure" *9th Berlin Worksop on Developmental Toxicology* (Federal Institute for Risk Assessment -BfR, Berlin, September 2018)
- Speeches at the *First Scientific Symposium Health and Climate Change* (Istituto Superiore di Sanità. December 2018) on: "Climate changes and One Health. Examples from the safety assessment of primary production" and "Identifying and preventing climate change threats adversely affecting seafood production, nutritional value and safety "
- "Do PFOS/PFOA levels in Italian women pose a risk to fetal growth?" *47th Conference of the European Teratology Society* (Koln, September 2019. Abstract: A. Mantovani, F. Baldi, P. Salerno, D. Taruscio, Reproductive Toxicology, 2019, 88, Sept 2019: 16-17)
- "Presentation of a Regulatory Authority", invited lecture at the *Third workshop "Towards Chemical Pesticide-free Agriculture*" (Natural Resources Institute Finland - Helsinki, 2019)
- "Health risk assessment of EDC in food chains" invited lecture at the "*2nd Africa Conference on Health Effects of Endocrine Disruptors*" (Pretoria, Republic of South Africa, 2019)
- "View of a developmental toxicologist from the EU on the Japanese proposal" 10th *Berlin Workshop on Developmental Toxicology* (BfR, Berlin February 2020)
- "Current Challenges in EDC Risk Assessment" invited talk at the *6th Asia-Pacific Symposium on Food Safety* (South Korea, November 2021)
- Panelist at the Affidia International Webinar "*Mycotoxins EU regulations: are the limits too strict, too weak, or just fine?*" (December 2021)

2008-2017 (February)

Reseach Director – director of the Food and Veterinary Toxicology Unit (TAV) – Dept Food Safety and Veterinary Public Health (SPVSA)- Istituto Superiore di Sanità (ISS)

Main activities and roles

From January 2008 to February 2017 I directed the Food and Veterinary Toxicology

(TAV) Unit in the new Department of Veterinary Public Health and Food Safety, directed by Agostino Macrì. The TAV Unit was also a new structure, stemming from the aggregation of different skills (toxicology, molecular biology, analytical chemistry, biosensors) and which contributed to the relaunch and renewal of the ISS expertise and activity in toxicological risk assessment. Actually the TAV Unit was born in response to the need, highlighted by the Director of the Department, to organize a structure specifically dedicated to the assessment of potential health risks from additives, residues and contaminants in food chains. Besides myself, a total of 1 senior and 3 junior staff researchers, 6 researchers anf 3 skilled technicians hired on grants worked in the structure as well as doctoral students and undergraduates.

The *research activity*, while maintaining a strong interest on the topic of endocrine disruptors - always a priority at an international level - has also developed on other *emerging topics*, on which the increase of knowledge is necessary for a more solid and accurate evaluation of the risk: pesticides and biocides; trace elements and nanomaterials; development of animal-free tests and biomarkers; and "one health" approaches to the environment-food-health complex. It was important to acquire the collaboration with *medical centers of excellence*, which led to innovative results in the fields of epidemiology and biological monitoring of exposure to pollutants.

The *institutional* activity has focused on aspects of *toxicological risk assessment* in different areas. The main activities concerned:

- the toxicological assessment of chemicals in Europe (*Biocides*; Competent Authority for *REACH regulation* on substances present in the living and working environment),

- the *European Food Safety Authority* (EFSA) in the FEEDAP panels (substances used in animal feed, 2008-12 and 2015-18; vice.chair in 2008-12 and chair of the Trace Elements working group), PPR (plant protection products, 2012-15) and collaborations with the Scientific Committee and other Panels, with an abundant production of opinions and guidelines;

- the *National Food Safety Committee* (2011-13 and 2015-18 with opinions concerning, for example, the radionuclide Thorium in the Sardinia region and the release of aluminum from materials in contact with food).

- documents produced for the *Ministry of Health* (contribution to the Report on the State of Health of the Country and to Expo 2015) and for the *National Committee on Biosafety, Biotechnology and Life Sciences attached to Prime Minister Office* (Document "Proposal for an Environment-Health program, 2010)

- Interventions in environmental exposure scenarios, such as: (a) Interdisciplinary Group on Environment and Health in the *risk area of Gela*; (b) Evaluation of the human health risk related to edible marine organisms following the sinking of drums containing toxic material off the *Gorgona Island*: (c) *Arsenic in the water* bodies of Lazio; (d) exposure to *pesticides in the intensive viticulture areas* of Trentino and collaboration with the Autonomous Province for a sustainable use

- ad hoc working groups organized by international agencies; among these, of particular interest for the protection of health in Europe are the recommendations for the primary prevention of congenital malformations (published in *Public Health Genomics*, 2014) and the international consensus document on the identification of endocrine disruptors (published in *Archives of Toxicology* 2017).

From the point of view of *managerial experience*, in addition to the regular management of the structure (including the regularization of grant-hired colleagues, who all have had fixed-term contracts and now all have entered as permanent staff) the management of the TAV Unit has be encharacterized by the following endeavors (see List for details)

a) contribution to the role of the ISS as a *portal of scientific knowledge*, through the maintenance and development of the thematic web-area Endocrine Disruptors, of the EDID database - first database on the interactions between nutrients and contaminants - and of thematic areas linked to projects (PREVIENI, PERSUADED and LIFE EDESIA);

b) attention to the *transfer of knowledge* to the NHS through (a) the project activities commissioned by the Ministries of Health and of Environment, among which is prominent the PREVIENI project, funded by the Min. Environment and (b) the production of ISS documents, including materials for risk communication, as well as the organization of courses and workshops;

c) *patenting activity*, in collaboration with enterprises on public health objectives, through the development of the ISS BEST patent and the ALERT project, funded by the Ministry for Economic Development

d) *international collaboration*, obviously primarily with European centres, but also with Developing Countries, as also highlighted by international publications;

e) last but not least, the *empowerment of younger researchers*, from the point of view of both the responsibility for project, patent activities (see *Mentoring* in the List), as well as the institutional activities, including: Francesco Cubadda, Italian representative in the EFSA NanoNetwork; Cinzia La Rocca and Francesca Maranghi among the Italian experts participating in the OECD activities on updating the guidelines for toxicological tests and the evaluation of endocrine disruptors; Stefano Lorenzetti in the National Group of Alternative Methods Experts, organized at the Zooprophylactic Institute of Brescia, and among the Italian experts in support of the Competent Authority for REACH; Roberta Tassinari, grant researcher, in the ISS Expert group for Biocides.

Quality assurance of activities and *safety in the workplace* have been an important aspect in TAV Unit management. The needs to ensure the quality of the experimental activities for the exposure assessment of trace elements and nanomaterials - one of the main skills developed by the TAV Unit - and to guarantee the maximum protection of safety in the workplace has led to the establishment of the *Clean Room for the analysis of trace elements and nanomaterials*. The structure was put in place also thanks to my commitment in building a shared path with the Prevention and Protection Service and the Logistics, Design and Maintenance Office. The success of the initiative is indicated by the appointment (2021) of the ISS, thanks to the establishment of this structure, as a National Reference Laboratory for nanomaterials.

2003-2007

Senior Staff Scientist (2003-2006), Research Director (since 2007) – Dept of Food Safety and Animal Health (SAAN), ISS

Main activities and roles

The move from the TCE laboratory to the SAAN Dept. represented the challenge in adapting the topics developed in the TCE laboratory to the emerging field of risk assessment in food safety: my group (a researcher and a staff skilled technician in addition to myself) was included in the Unit "Chemical risk in the production chains and quality of control" (director Rosa Draisci).

The research activity focused mainly on *endocrine disruptors*, but also on other topics of risk assessment, including pesticides and biocides and methodological advances, expanding the network of collaborations inside and outside the ISS.

In addition to the continuation of participation in OECD activities, institutional activities in the field of risk assessment saw new developments:

- participation as co-chair of the "endocrine disruptors" group in the elaboration of the *European Environment and Health Strategy*,
- expert in the European Food Safety Authority (EFSA) both as a member of the FEEDAP panel (safety of substances used in feed, since 2003) and with collaborations with the Scientific Committee and the Contaminants Panel.

In the Italian context, new tasks included
- chair of the Working Group "*Surveillance of Exposure to Endocrine Disruptors*" of the National Committee for Biosafety and Biotechnology attached to the Prime Minister office;
ISS expert at the "Technical-scientific committee" for the evaluation of the risk for human health, related to the presence in the soil of toxic substances, PCBs and mercury, *in the Caffaro area of the Municipality of Brescia*.

The construction of a managerial experience consisted, first of all, in the expansion of the skills of the group with the acquisition of grant-hired staff with different skills (molecular biology, communication, analytical chemistry), in order to build a competent structure and reliable of toxicology.
I also contributed to the role of the ISS as a portal of scientific knowledge, through the creation of the t*hematic area Endocrine Disruptors* on the ISS site, which since 2006 also contains the EDID database - the first database on interactions between nutrients and contaminants (see List, 3.2.2). The transfer of knowledge to the SSN was supported by means of the production of ISS documents.
Above all I have given a strong attention to the sustainability of scientific activity, through participation in *projects of the 6th Framework Program* (see List).
Alongside these, the networking activity with the structures of the health and scientific world was supported through the organization of scientific and training events and interventions at national and international meetings (see *List*, for the respective items)

1987-2002

Junior staff scientist (1987-1991), Senior staff scientist (1992-2002) in the Laboratory of Comparative Toxicology ed Ecotoxicology (TCE), ISS

Main activities and roles

In the TCE Laboratory, a multidisciplinary structure on the different aspects of environmental toxicology, my primary activity was centered - following the indication of the then director prof. Vittorio Silano - on the construction of an operational unit dedicated to a competence not present in the ISS until then: *reproductive and developmental toxicology*.
This competence has also developed thanks to internships at the Un. Statale di Milano (Prof. Erminio Giavini, 1986) and the Frei Universitat of Berlin (Prof. Dieter Neubert, 1988-89).
To this, I accompanied the training in Good Laboratory Practice and quality assurance systems thanks to the *OECD courses* of 1988 and 1999.
At the same time, reproductive toxicity is a branch of toxicological risk assessment; therefore, collaborations have been developed, both in the field of experimental toxicology (organ toxicity and toxicity mechanisms, including toxicological studies to characterize the adverse effects of *benzotrifluorides,* environmental contaminants originating from industrial emissions in the province of Vicenza) and in the broader field of One Health ("Environment is health"), starting the collaboration with medical expertises. In this context with my group we have contributed toxicological skills to the national interdisciplinary project, coordinated by the ISS, "*Prevention of risk factors in maternal and child health*".

At the end of the 90s, upon the indications of the then director of the TCE Laboratory -Angelo Carere- and of the director of the ISS -Giuseppe Benagiano, I began to deal with an emerging (and still today) priority topic in the field of environmental safety, *endocrine disruptors*.
On this emerging sector, I coordinated the *national pilot project* of finalized research, *funded by the Ministry of Health*, which integrated groups of the Academy, of the research bodies and of different ISS structures; thanks to this initiative, our Institute conquered the role of scientific reference point for this issue
The results of the activity translated into
- scientific production, as shown by international publications
- institutional activity, with the production of ISS documents (methodologies, evaluations, informative materials) and participation in risk assessment activities at national level (*National Toxicological Advisory Commission*, *Plant Protection Products Advisory Commission*),
European level: *Specialized Experts in the Field of Mutagenic, Carcinogenic and Teratogenic Substances*, as well as Safety of Residues Working Party at EMEA, the preparation of criteria for the classification of substances as toxic to reproduction and the criteria to assess biocides (EU Biocide directive)
participation as Italian expert in the *OECD Encocrine Diruptor Testing and Assessment Working Group* (EDTA).

As for building a managerial experience, the main step was the coordination of the national endocrine disruptors project, already mentioned.
In addition, the organization of national and international scientific and training events. including the *24th Conference of the European Teratology Society*

1983-1986

Junior scientist in the Laboratory Animal Unit, ISS

Main activities and roles

In this first role in ISS, my responsibility consisted in assisting the management of the central structure of the ISS dedicated to animal testing (at the time "Stabulary Service") by keeping the international quality criteria and supporting with my skills of DVM skilled in pathology several research groups of the ISS that conducted in vivo research on chemical substances.
The issues addressed (aluminum, mycotoxins, hepatotoxicity) and the publications produced, also in the following years, represented the first basis for building my competence in the evaluation of toxicological risk.

LIST of PUBLICATIONS, DOCUMENTS AND ACTIVITIES

1. INTERNATIONAL *PEER-REVIEWED* SCIENTIFIC PAPERS
(last twelve years: 2011-2022)
divided by topic, in chronological order

A) Risk assessment: Endocrine Disruptors

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.

1) 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.

2) Maranghi F, Mantovani A (2012). Targeted toxicological testing to investigate the role of endocrine disrupters in puberty disorders. *Reprod Toxicol*. 33: 290-6.

3) Caserta D, Bordi G, Ciardo F, Marci R, La Rocca C, Tait S, Bergamasco B, Stecca L, Mantovani A, Guerranti C, Fanello EL, Perra G, Borghini F, Focardi SE, Moscarini M (2013). The influence of endocrine disruptors in a selected population of infertile women. *Gynecol Endocrinol.* 29: 444-7.

4) Caserta D, Bordi G, Guerranti C, Fanello EL, Perra G, Borghini F, La Rocca C, Tait S, Bergamasco B, Stecca L, Marci R, Lo Monte G, Soave I, Mantovani A, , Focardi SE, Moscarini M (2013). Correlation of endocrine disrupting chemicals serum levels and white blood cells gene expression of nuclear receptors in a population of infertile women. *Int J Endocrinol,* doi: 10.1155/2013/510703. Epub 2013 Apr 21.

5) Maranghi F, De Angelis S, Tassinari R, Chiarotti F, Lorenzetti S, Moracci G, Marcoccia D, Gilardi E, Di Virgilio A, Eusepi A, Mantovani A, Olivieri A (2013). Reproductive toxicity and thyroid effects in Sprague Dawley rats exposed to low doses of ethylenethiourea *Food Chem Toxicol* 59: 261-71.

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.

7) Maranghi F, Tassinari R, Mantovani A (2013). Toxicological assessment of drugs that effect the endocrine system in puberty-related disorders. *Expert Opin Drug Metab Toxicol* 9: 1309-16.

8) Caserta D, Di Segni N, Mallozzi M, Giovanale V, Mantovani A, Marci R, Moscarini M (2014). Bisphenol A and the female reproductive tract: an overview of recent laboratory evidence and epidemiological studies. *Reprod Biol Endocrinol.* 12: 37 doi: 10.1186/1477-7827-12-37.

9) Fucic A., Mantovani A (2014). Puberty dysregulation and increased risk of disease in adult life: possible modes of action. *Reprod Toxicol* 44C: 15-22.

10) 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 disrupters and nuclear receptors gene expression in infertile and fertile women from different Italian areas. *Int J Environ Res Public Health*. 11: 10146-164.

11) Smeriglio A, Trombetta D, Marcoccia 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 Med Chem.* 14: 1386-96

12) Del Pup L, Mantovani A, Luce A, Cavaliere C, Facchini G, Di Francia R, Caraglia M, Berretta M (2015). Endocrine disruptors and female cancer: informing the patients. *Oncol Rep* 34: 3-11

13) 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. T*oxicol in Vitro* 29: 1021-5

14) Lorenzetti S, Marcoccia D, Mantovani A (2015). Biomarkers of effect in endocrine disruption: how to link a functional assay to an adverse outcome pathway. *Annals of the ISS* 51: 167-71

15) 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

16) Tait S, Tassinari R, Maranghi F, Mantovani A (2015). Bisphenol A affects placental layers morphology and angiogenesis during early pregnancy phase in mice. *J Appl Toxicol.* 34: 1278-91

17) Tassinari R, Mancini FR, Mantovani A, Busani L, Maranghi F (2015). Pilot study on dietary habits and life-styles of girls with idiopathic precocious puberty from the city of Rome: potential impact of exposure to flame retardant polybrominated diphenyl ethers. *J Pediatr Endocrinol Metab.* 28: 1369-72.

18) 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 disrupters and nuclear receptors gene expression in infertile and fertile men from Italian areas with different environmental features. *Int J Environ Res Public Health.* 12: 12425-45.

19) Fucic A, Mantovani A (2015). Gender and age related modulation of xenoestrogen-induced tumorigenesis. *The Open Biotechnology Journal*, 9; doi:10.2174/1874070720151112E016

20) 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. (2015) Parma Consensus Statement on Metabolic Disruptors. *Environ Health* Jun 20;14:54. doi: 10.1186/s12940-015-0042-7.

21) Del Pup L, Mantovani A, Cavaliere C, Facchini G, Luce A, Sperlongano P, Caraglia M, Berretta M (2016). Carcinogenetic mechanisms of endocrine disruptors in female cancers. *Oncol Rep* 36: 603-12.

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23) Mantovani A (2016). Endocrine Disrupters and the safety of food chains. *Horm Res Paediatr*. 86: 279-88.

24) Stecca L, Tait S, Corrado F, Esposito M, Mantovani A, La Rocca C (2016). Development of an in vitro test battery model based on liver and colon cancer cell lines to discriminate PCB mixtures by transcription factors gene expression analysis. *Toxicol in vitro* 34:204-21

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27) Medda E, Santini F, De Angelis S, Franzellin F, Fiumalbi C, Perico A, Gilardi E, Mechi MT, Marsili A, Citroni A, Leandri A, Mantovani A, Vitti P, Olivieri A (2017). Iodine nutritional status and thyroid effects of exposure to ethylenebisdithiocarbamates. *Environ Res*. 154:152-159.

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B) ***Risk assessment: xenobiotics, natural substances, mixtures*** *(trace elements, substances relevant to the agricultural productions, nanomaterials) in the environment and food production chains*

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1.1 SELECTED INTERNATIONAL *PEER-REVIEWED PAPERS published before 2011* *(divided by topic, in chronological order)*

A) ***Risk assessment****: substance in the environment, consumer products and food production chains*

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*C) "**Environment is Health" and One Health**: methodologies and concepts for risk analysis*

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1.3 Other International Publications:

Books

Mantovani A, Fucic A (editors) "*Challenges in Endocrine Disruptor Toxicology and Risk Assessmen*t" Royal Society of Chemistry, Londra (2020,) .
Within this book, co-author of
(Chapter 3) Mantovani A "*Issues for hazard characterizattion of endocrine disrupting chemicals: the use of Adverse Outcome Pathways"*
(Chapter 13) Cernelev O, Mantovani A: "*Natural substances in supplements and nutraceuticals as Endocrine Disruptors"*
(Chapter 15) Catone T, Attias L, Mantovani A "*Endocrine Disrupting Chemicals in clothing and cosmetics*"
(Chapter 19) Fucic A, Mantovani A, Montano L *"Interdisciplinary collaboration between environmental health and clinical experts on cancers and infertility*

associated with the exposure to endocrine disruptors"

Book Chapters

1) Mantovani A., Cozzani R. (2006) *Risk assessment of feed additives and contaminants*. In "Towards a risk-based chain control. Vol.4- Food Safety assurance and veterinary public health" (ed. Frank J. Smulders), Wageningen Academic Publishers, the Netherlands, pp. 45-56

2) Mantovani A., Frazzoli C, La Rocca C. (2007) R*isk assessment of endocrine disruptors: the feed-to-food chain*. In "The Endocrine Disruptors" (ed by M. Marino & D.G. Mita) . Transworld Research Network, (Trivandrum-Kerala, India), pp. 113-128.

3) Mantovani A., Maranghi F. (2007) *Endpoints for Prenatal Exposures in Toxicological Studies*. In Congenital Diseases and the Environment (Series: Environmental Science and Technology Library , Vol. 23, Nicolopoulou-Stamati, P.; Hens, L.; Howard, C.V. Eds.), Springer, Dordrecht (NL), pp. 21-36.

4) Rescia M., Mantovani A. (2007). *Pesticides as Endocrine Disrupters: Identification of Hazards for Female Reproductive Function*. In Reproductive Health and the Environment. Series: Environmental Science and Technology Library, Vol. 22. Nicolopoulou-Stamati, P.; Hens, L.; Howard, C.V. (Eds.). Springer, Dordrecht (NL), pp. 227-48

5) Mantovani A, Proietti I (2011). *Occurrence of endocrine disrupters in food chains*. In: Hormone-Disruptive Chemical Contaminants in Food (ed by Ingemar Pongratz and Linda Bergander). Issues in Toxicology, n. 9. RSC Press, 199-215.

6) Mantovani A. (2012) *Chemical risk assessment of animal feed*. In: Animal feed contamination: Effects on livestock and food safety (ed. by Johanna Fink-Gremmels). Woodhead Publishing Series in Food Science, Technology and Nutrition No. 215. pp. 449-63.

7) Mantovani A (2012). *Endocrine Disruptors and Puberty Disorders from Mice to Men (and Women)*. In: Endocrine Disruptors and Puberty (ed. by Evanthia Diamanti-Kandarakis and Andrea C. Gore). Contemporary Endocrinology Part 1, Springer, 119-137.

8) Lorenzetti S., Mantovani A (2014). *Reproductive and Developmental Toxicity Testing: issues for 3Rs implementation*. Chapter 17 in : Reducing, Refining and Replacing the Use of Animals in Toxicity Testing (Ed.by Dave Allen and Mike D Waters) Series: Issues in Toxicology ISSN: 1757-7179, Royal Society of Chemistry, London, UK pp. 330-347.

9) Proietti I, Mantovani A (2017). *Toxicological Risks of Waste Burning Residues in Foods: A View on Low-Income Countries* In "Food toxicology. Current Advances and Future Challenges" (A. Sachan and S. Hendrich, eds.), Apple Academic Press, USA and Canada, pp. 337-59.

10) Belluco S, Mantovani A, Ricci A (2018). *Edible insects in a food safety perspective*. In "Edible Insects in Sustainable Food Systems" (Halloran A., Flore R., Vantomme P, Roos N., Eds.) .), Springer, Dordrecht (NL), pp. 109-26.

11) Mantovani A. *Endocrine Disrupters: A Review* (2018). in "Encyclopaedia of Food Chemistry" (ed. by Peter Varelis, Laurence Melton and Fereidoon Shahid), Elsevier, Vol.1, pp. 481-6.

2. International Risk Assessment Documents

2.1. Assessment of chemical substances in wrkplace and environment (reproductive/developmental toxicity, endocrine disruption) -*European Chemicals Agency (ECHA)*

1) Dichlorvos (reproductive and developmental toxicity), EU Regulation on Biocides (2012)

2) Epoxiconazole (reproductive and developmental toxicity), Committee for Risk Assessment-RAC (2012)

3) Methoxyacetic acid (reproductive toxicity, endocrine disruption), Member State Committee for the identification of Substances of Very High Concern (2012)

4) Tetrakis (Hydroxymethyl) Phosphonium Sulfate (reproductive and developmental toxicity), EU Regulation on Biocides (2012)

5) Brodifacoum and other 2nd-generation anticoagulant rodenticides (developmental toxicity), EU Regulation on Biocides (2013)

6) Boric Acid (reproductive and developmental toxicity), Committee for Risk Assessment-RAC (2014)

7) Methanol (developmental toxicity), Committee for Risk Assessment-RAC (2014)

8) Qaternary Ammonium Salts (Alkyl Dimethyl Benzyl Ammonium Chloride – ABDAC, Didecyldimethylammonium chloride – DDAC: reproductive and developmental toxicity), EU Regulation on Biocides (2011-2015)

9) Chloromethane (developmental toxicity endocrine disruption), Substance Evaluation - Conclusion (2017)

10) Octabenzone (tossicità riproduttiva e interferenza endocrina), Substance evalutation - Conclusion (2018)

11) Tert-butyl perbenzoate (reproductive and developmental toxicity), Substance evalutation-Conclusion (2020)

12) Assessment of ABDAC and DDAC as possible endocrine disruptors for human health and the environment, EU Regulation on Biocides i (2020)

13) Hexafluoropropene (reproductive and developmental toxicity), Substance evalutation-Conclusion (2020)

2.1.2. European Food Safety Authority (EFSA)

- Member of the *FEEDAP Panel* (*Additives and Products or Substances used in Animal Feed*; http://www.efsa.europa.eu/en/panels/feedap) in the periods 2003-2012 and 2015-2018 in regard of the on the evaluation of the safety of substances used in animal feeds for *animals, consumers, users/workers and the environment* external expert in the Working Groups on Trace Elements and Vitamins in Feedingstuffs in the period 2012-15. Currently (from June 2019) external expert in the new Working Groups: Nutritional Additives, Other Additives and (from January 2020) in the Working Group Toxicology

- Member of the Panel PPR (*Plant Protection Products and their Residues*; https://www.efsa.europa.eu/en/panels/ppr), on the risk assessment of active principles for plant protection use in relation to human health *(dietary, occupational , environmental exposures) and ecosystems*, in the period 2012-2015. I also continued the contribution as an external expert until the adoption of the document - June 2016 - in the working group on "Experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukemia".

- External expert in working oups of the EFSA SCientific Committee and other Panels

(see below)

Please note. All panel members adopt an opinion and are therefore co-authors. Furthermore, all EFSA opinions are published in the *EFSA Journal*, available online and cited in PubMed starting from 2017.

Actually, the main authors of the opinions are the members of the working groups who prepare the draft to be presented to the Panel at the plenary meeting. Therefore, in the following paragraphs I present the opinions to which I contributed as *coordinator or member of the respective work groups*.

Opinions and documents of the Panel FEEDAP (feeds)

1) Safety of Nitarsone (4-nitrophenylarsonic acid) (organic arsenic compound, 2004)

2) Use of Iodine in feedingstuffs (2005); (2.1) safety and efficacy of Iodine compounds (E2) as feed additives for all species (2013)

3) Safety and efficacy of Benzoic Acid: (3.1) piglets (2005); (3.2) pigs for fattening (2007); (3.3) pigs for reproduction (2012); (3.4) minor porcine species (2017) ; (3.5) renewal of authorisation for weaned piglets and pigs for fattening (2017); (3.6) pigs and poultry, as feed flavouring for (2018); (3.7) pigs for fattening, for improvement of performance parameters(2019)

4) Safety and efficacy of Selenium in selenized yeasts for all species: (4.1) product Sel-Plex 2000 (2006) 4.2) Selenium-enriched yeast (Saccharomyces cerevisiae NCYC R397) (2007); (4.3) Selsaf (Selenium enriched yeast from Saccharomyces cerevisiae CNCM I-3399) (2009); 4.4) SelPlex (organic form of selenium produced by Saccharomyces cerevisiae CNCM I) as a zootechnical additive (2011); (4.5) Assessment of the application for renewal of authorisation of selenomethionine produced by Saccharomyces cerevisiae CNCM I-3060 - selenised yeast inactivated (2018); (4.6) renewal of authorisation of selenomethionine produced by Saccharomyces cerevisiae NCYC R397 for all animal species (2019)

5) Safety and efficacy of Copper Chelates of amino acids as feed additives for all animal species: 5.1) Copper chelates of hydroxy analogue of methionine as feed additives for all species (2008; supplemental information for safety of target species and consumers, 2009) (5.2) Copper chelates of lysine and glutamic acid (2019)

6) Safety and efficacy of Manganese Chelates of amino acids as feed additives for all animal species: 6.1) Manganese chelate of hydroxy analogue of methionine (2008); (6.2) Consumer safety of Manganese chelate of hydroxy analogue of methionine for chickens for fattening (2009); 6.3) Manganese chelate of hydroxy analogue of methionine (2010); (6.4) Manganese chelate of amino acids, hydrate (2013); 6.5) Manganese chelates of lysine and glutamic acid (2020)

7) Safety and efficacy of Zinc Chelates of amino acids as feed additives for all animal species: (7.1) Zinc chelate of hydroxy analogue of methionine (2008); (7.2) Zinc chelate of hydroxy analogue of methionine (2009); (7.3) Zinc chelate of amino acids hydrate (2012) (7.4) Zinc chelate of methionine sulfate (2017; safety for target species, 2018); 7.5) Zinc-l-Selenomethionine (2018; additional information on safety for target species, 2018); (7.6) Zinc chelates of lysine and glutamic acid (2019)

8) Use of Cobalt compounds as additives in animal nutrition (2009): (8.2) Safety and efficacy as feed additives for all animal species: Cobaltous acetate tetrahydrate, basic cobaltous carbonate monohydrate and cobaltous sulphate heptahydrate (2012)

9) Safety and efficacy of Chromium Methionine as feed additive for all species (2009); (9.11) Safety and efficacy of chromium chelate of DL methionine for day cows (2020)

10) Safety and efficacy of Vitamin B6 as a feed additive for all animal species (2010)

11) Safety and efficacy of Vitamin E as a feed additive for all animal species (2010)

12) Safety and efficacy of Pantothenic Acid as a feed additive for all animal species (2011)

13) Safety and efficacy of vitamin B1 as a feed additive for all animal species (2011)

14) Safety of Hemp (Cannabis genus) for use as animal feed (2011)

15) Safety and efficacy of CRINA® Poultry Plus (preparation of Benzoic Acid and Essential Oil Compounds) as feed additive for chickens for fattening (2012)

16) Safety and efficacy of Beta-Carotene as a feed additive for all animal species and categories (2012)

17) Safety and efficacy of (inorganic) Copper compounds as feed additives for all animal species: cupric sulphate pentahydrate (2012)

18) Safety and efficacy of Folic Acid as a feed additive for all animal species (2012)

19) Safety and efficacy of Niacin (Nicotinic Acid and Nicotinamide) as a feed additive for all animal species (2012)

20) Safety and efficacy of Biotin as a feed additive for all animal species (2012)

21) Safety and efficacy of (inorganic) Zinc compounds as feed additive for all animal species (21.1) Zinc oxide (2012); (21.2) Zinc sulphate monohydrate (2012)

22) Safety and efficacy of Taurine as a feed additive for all animal species (2012)

23) Safety and efficacy of (inorganic) Manganese compounds as feed additives for all species: manganous oxide and manganous sulphate monohydrate (2013)

24) Safety and efficacy of Vitamin A (retinyl acetate, retinyl palmitate and retinyl propionate) as a feed additive for all animal species and categories (2013)

25) Safety and efficacy of Betaine as a feed additive for all animal species (2013

26) Safety and efficacy of Vitamin C as a feed additive for all animal species (2013)

27) Safety and efficacy of Vitamin D3 (Cholecalciferol) as a feed additive for pigs, piglets, bovines, ovines, calves, equines, chickens for fattening, turkeys, other poultry, fish and other animal species or categories (2014); (27.1) Safety of vitamin D3 addition to feedingstuffs for fish (2017)

28) Safety and efficacy of Vitamin B2 as Riboflavin produced by Bacillus subtilis for all animal species (2014)

29) Safety and efficacy of (inorganic) Iron compounds as feed additives for all species: (29.1) Ferrous sulphate heptahydrate (2014); (29.2) Ferric oxide (2016)

30) Safety and efficacy of Inositol as a feed additive for fish, dogs and cats (2014)

31) Safety and efficacy of vitamin K3 (Menadione sodium bisulphite and Menadione nicotinamide bisulphite) as a feed additive for all animal species (2014)

32) Safety and efficacy of Phaseolus vulgaris Lectins as a zootechnical additive for suckling piglets (performance enhancer) (2015

33) Safety of Solanum glaucophyllum standardised leaves as feed material (2015)

34) Safety and efficacy of (inorganic) Selenium compounds as feed additives for all animal species: (34.1) sodium selenite (2015); (34.2) sodium selenate for ruminants (used as intraruminal bolus) (2019)

35) Safety and efficacy of Methylester of Conjugated Linoleic Acid (t10,c12 isomer) for pigs for fattening, sows and cows (2016); (35.1) for sows and cows for reproduction

(2019)

36) Safety of Lanthanide Citrate (Lancer) as a zootechnical additive for weaned piglets (2016

37) Safety of l-Tryptophan for all animal species: (37.1) produced by fermentation with Escherichia coli DSM 25084, KCCM 11132P and SARI12091203 for all animal species (2017); (37.2) produced by Escherichia coli CGMCC 7248 for all animal species (2019); (37.3) produced by fermentation with Escherichia coli KCCM 10534 (2020)

38) Safety and efficacy of L-Arginine produced by fermentation with Escherichia coli NITE BP-02186 for all animal species (2018)

39) Safety and efficacy of Vitamin B12 (in the form of Cyanocobalamin) produced by Ensifer spp. as a feed additive for all animal species (2018)

40) Safety and efficacy of Fumonisin Esterase from Komagataella phaffii DSM 32159 as a technological feed additive for pigs and poultry (2018)

41) Safety and efficacy of Ferric Tyrosine Chelate as a zootechnical feed additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breading (2019)

42) Safety and efficacy of Ferric Tyrosine Chelate as a zootechnical feed additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breading (2019)

43) Safety and efficacy of a Molybdenum compound: sodium Molybdate dihydrate as feed additive for sheep (2019)

44) Safety and efficacy of l-Threonine produced by fermentation with Corynebacterium glutamicum for all animal species (2019)

45) Safety and efficacy of Biomin (blend of essential oils from oregano (Origanum vulgareL.) and caraway seed (Carum carviL.), Carvacrol, methyl Salicylate, L-menthol) as a zootechnical feedadditive for weaned piglets (2019)

46) Safety and efficacy of l-Lysine: (46.1) l-Lysine monohydrochloride and concentrated liquid l-Lysine (base) produced by fermentation using Corynebacterium glutamicum strain KCCM 10227 for all animal species (2019) (46.2) L-Lysine monohydrochloride and L-Lysine sulfate produced using Corynebacteriumglutamicum CGMCC 7.266 for all animal species (2020);

47) Safety and efficacy of l-Leucine produced by fermentation with Escherichia coli NITE BP-02351 for all animal species (2019)

48) Safety and efficacy of Iron Chelates of amino acids for all animal species: iron chelates of lysine and glutamic acid (2019)

49) Safety and efficacy of l-Histidine monohydrochloride monohydrate: (49.1) produced using Corynebacterium glutamicum KCCM 80172 for all animal species (2019) (49.2) produced by fermentation with Escherichia coli (NITE BP-02526) for all animal species (2019); 49.3) renewal of authorisation of L-histidine monohydrochloride monohydrate producedwith Escherichia coli NITE SD 00268 for salmonids and itsextension of use to other fin fish (2020)

50) Safety and efficacy of Carvacrol as a zootechnical additive for weaned piglets (2020)

51) Safety and efficacy of Stabilflor (Zinc EDTA and Copper EDTA) as a zootechnical feed additive for pigs for fattening (2020)

52) Chesson A, Gropp J, Mantovani A, Roncancio C; Special issue: Ten years of EFSA's FEEDAP Panel and its main achievements. *EFSA Journal* 2012;10(10):s1005. [9 pp.]

53) Guidance on the assessment of the safety of feed additives for the target species (2017) https://www.efsa.europa.eu/en/efsajournal/pub/5021

54) Guidance on the assessment of the safety of feed additives for the consumer (2017) https://www.efsa.europa.eu/en/efsajournal/pub/5022

Opinions and documents of the Panel PPR (pesticides)

55) Identification of pesticides to be included in Cumulative Assessment Groups on the basis of their toxicological profile (2013)

56) Relevance of dissimilar mode of action and its appropriate application for Cumulative Risk Assessment of pesticides residues (2013)

57) Developmental neurotoxicity potential of Acetamiprid and Imidacloprid (2013)

58) Good modelling practice in the context of Mechanistic Effect Models for Risk Assessment of plant protection products (2014)

59) Guidance on the establishment of the Residue Definition for Dietary Risk Assessment (2016: Working Group member till June 2015)

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

Panel on Contaminants in the Food Chain (CONTAM)

61) Health risks to consumers associated with exposure to Organotins in foodstuffs (2004)

Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

62) Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A (2010)

Panel on Genetically Modified Organisms (GMO)

63) Review of the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology (referee del documento EFSA con A. Chesson)

Scientific Committee and Emerging Risks

64) Existing approaches incorporating Replacement, Reduction and Refinement of animal testing (2009)

65) Data collection for the identification of Emerging Risks related to food and feed (2011)

66) Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC) (2012)

67) Technical Report. A Systematic Procedure for the identification of Emerging Chemical Risks in the food and feed chain (2015)

68) Technical Report. Identification of Emerging Risks: an appraisal of the procedure trialled by EFSA and the way forward (2015)

2.1.3 OECD

I am member of the OECD Working Group on Endocrine Disrupters Testing and Assessment (EDTA) from 2000-to date.

Within EDTA, I am also member of the Validation Management Gr*oup* of the screening assays.

1) OECD Environment, Health and Safety Publications Series on Testing and Assessment No. 150. G*uidance Document on Standardised Test Guidelines for evaluating chemicals sor Endocrine Disruption* ENV/JM/MONO(2012)22

2) OECD Environment, Health and Safety Publications Series on Testing and Assessment. *Revised Guidance Document 150 on Standardised Test Guidelines for evaluating chemicals for Endocrine Disruption* (September 2018; component of the Steering Committee)

3) Nordic Report "*Retinoids in Mammalian Reproduction, with an Initial Scoping Effort to Identify Regulatory Methods*". Nordic Co-operation20/04/2020 (delivered by the working group OECD constituted in 2017)

2.1.4 Other international documents

1) European Environment and Health Strategy (COM(2003)338 final) R*eport on Actions and Recommendations for "Integrated Monitoring of Endocrine Disrupters"* (Chair of the Working Group with J. Tarazona);

2) Report of the Independent Scientific Peer Review of the *LUMI-CELL® ER (BG1Luc ER TA) Test Method* organized by the UA Interagency Coordinating Committee on the Validation of Alternative Methods –ICCVAM; National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods –NICEATM; Us. National Institute of Environmental Health Sciences –NIEHS ((Member of the Panel) . (2011)

3) EUROCAT - EUROPLAN. *Recommendations on policies to be considered for the primary prevention of congenital anomalies in National Plans and Strategies on Rare Diseases* (adopted by EUCERD – now EC Expert Group on Rare Diseases- nel 2013) (Member of Expert Group) http://www.eucerd.eu/wp-content/uploads/2013/03/Eurocat_Reco_PrimaryPrevention.pdf

4) Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). *Hazards associated with animal feed*. (Member of Expert Group) Joint FAO/WHO expert meeting. FAO Animal Production and Health / Report 14, 2019.

5) Contribution to the document of the *European Economic and Social Committee* commenting the EC communication on "Towards a more comprehensive EU framework on endocrine disruptors" (raporteur Brian Curtis, NAT/754-EESC-2018, March 2019) https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/towards-more-comprehensive-eu-framework-endocrine-disruptors

6) *Scientific package to support "Layman's package on health benefits for consumers from selected eco-innovative solutions developed by SeaFoodTomorrow*". Deliverable 3.6of the project *SeaFoodTomorrow*. (30/10/2020) publicly available at https://seafoodtomorrow.eu/wp-content/uploads/2021/04/SEAFOODtomorrow_D3.6_Scientific-package-to-support-WP6_v1.pdf

7) *Policy brief: One Health-Based Conceptual Frameworks for Comprehensive and Coordinated Prevention and Preparedness Plans Addressing Global Health Threats* in support of the Task Force 1 "Global Health and COVID-19" T20 -G20 (September 2021) 7.a) also published as: M.G. Dente, F. Riccardo, S. Declich, A. Milano, C. Robbiati, U. Agrimi, A. Mantovani, S. Morabito, G. Scavia, F. Cubadda, L. Villa, M. Monaco, L. Mancini, M. Carere, S. Marcheggiani, A. Lavazza, M. Farina, O. Dar, M. Villa, P. Testori Coggi, S. Brusaferro (2022) Strengthening preparedness against global health threats: A paradigm shift based on One Health approaches. *One Health*, 14, doi.org/10.1016/j.onehlt.2022.100396.

International Documents of the Istituto Superiore di Sanita'

1) (a) Tait S, La Rocca C, Mantovani A"Risk factors investigation in the pathogenesis of the bladder extrophy-epispadias complex" (pp. 40-2); b) Salvatore M, Magrelli A, Viganotti M, Tosto F, Azzalin G, Antoccia A, Di Masi A, Devito R, Lorenzetti S, Maranghi F, Macino G, Mantovani A, Tanzarella C, Taruscio D. "Tackling rare diseases yet lacking diagnosis and/or prognosis. A pilot project integrating data collection and experimental studies: the hepatoblastoma experience" (pp. 56-8). In: D. Taruscio, M. Salvatore (a cura di) "*ISS-NIH collaborative programme on rare diseases: reports of the projects*". 2010. Rapporti ISTISAN 10/12.

2) a) C. Frazzoli, S. Lorenzetti, A. Mantovani "Sustainable food safety and trans-generational health outcomes in developing economies" (pp. 27-33); b) A. Mantovani "Feed for food: feed components at the food security-food safety interface" (pp. 52-9); c) G.B. Pouokam, G. Chukwuebuka Ajaezi, C. Frazzoli, O.E. Orisakwe, A. Mantovani "Dumping of banned baby bottles from advanced economies: an overlooked hazard for African infants?" (pp. 180-8). In: Frazzoli C, Asongalem EA, Orisakwe OE (a cura di) "*Cameroon-Nigeria-Italy scientific cooperation: veterinary public health and sustainable food safety to promote "one health/one prevention*". 2012. Rapporti ISTISAN 12/49,

3) Cubadda F, Aureli F, D'Amato M, Raggi A, Mantovani A (eds). *Conference. Nanomaterials in the food sector: new approaches for safety assessment*. Rome, Istituto Superiore di Sanità. September 27, 2013. Proceedings. 2013. Rapporti ISTISAN 13/48 (37 pp.).

4) Cubadda F, Aureli F, Raggi A, Barea Toscan MC, Mantovani A. Second National Conference. *Nanotechnologies and nanomaterials in the food sector and their safety assessment*. Istituto Superiore di Sanità. Rome, April 29, 2016. ISTISAN Congressi 16/C2 (39 pp.)

5) a) A. Mantovani "Climate changes and "one health". Examples from the safety assessment of primary production" (p. 152); b) F. Cubadda, F. Aureli, M. Silano, A. Mantovani "Identifying and preventing climate change threats adversely affecting seafood production, nutritional value and safety" (p. 154). "*First Scientific Symposium Health and Climate Change*" (ed. by W. Ricciardi, S. Marcheggiani, C. Puccinelli, M. Carere, T. Sofia, F. Giuliano, E. Dogliotti and L. Mancini) ISTISAN Congressi 18/C5

6) Working group ISS-INAIL (2020) *Focus on the professional use of ozone also in reference to COVID-19*. Series of Reports ISS COVID-19, 56/2020

3. SCIENTIFIC COMMUNICATION at international level

1) Mantovani A. Emerging Contaminants. *The Analytical Scientist*, February 2013

2) Mantovani A. Toxic Cocktails . *The Analytical Scientist*, March 2014

3) Mantovani A, Lorenzetti S. LIFE-EDESIA: Endocrine Disruptors in silico/in vitro - Evaluation and Substitution for Industrial Applications. *The Parliament Magazine* Issue 436 | 13 June 2016:45.

4) Collaborations with the international governance magazine on-line *Open Access Government* (London, UK) (2016-2020)

4.1) (Mantovani A) The value of research into endocrine disrupting chemicals (September 2016)
4.2) (Mantovani A, Baldi F) Endocrine Disrupters: To Assess Or Not To Assess? (e-books series: October 2016)
4.3) (Mantovani A, Baldi F) The Importance of Communicating Earnest on EDC (December 2016)
4.4) (Mantovani A, Baldi F) Through the looking-glass: Endocrine disruption and child health (March 2017)
4.5) (Mantovani A, Frazzoli C) Endocrine disrupting chemicals: from feeds to hormones (May 2017)
4.6) (Mantovani A) Understanding the adverse outcome pathway concept (August 2017)
4.7) (Mantovani A) New insights on reproductive toxicants (October 2017)
4.8) (Montano L, Mantovani A) Human sperm cells, the overlooked sentinel of our living environment (November 2017)
4.9) (Mantovani A) Chemicals impairing thyroid: a worthy concern for European risk assessors (December 2017)
4.10) (Mantovani A, Baldi F) The challenge of replacing hazardous substances (January 2018)
4.11) (Mantovani A) Endocrine disrupting chemicals; sustainability and/or resilience? (March 2018)
4.12) (Mantovani A) How to screen for endocrine disrupting chemicals (EDC) (April 2018)
4.13) (Mantovani A) Assessing endocrine disrupting chemicals (EDC) (April 2018)
4.14) (Mantovani A) Endocrine disrupting chemicals: The issue of mixtures toxicity assessment (June 2018)
4.15) (Mantovani A) The European Commission roadmap: Towards a More Comprehensive EU Framework on Endocrine Disruptors (September 2018)
4.16) (Mantovani A) A Network of Knowledge on Endocrine Disrupting Chemicals: the debate at the European Teratology Society (October 2018)
4.17) (Mantovani A, Baldi F) Endocrine disrupters: a network of knowledge (e-book series, October 2018)
4.18) (Mantovani A) The European Commission takes action on endocrine disruptors: A call for a multidisciplinary network (November 2018)
4.19) (Mantovani A) Climate changes, risk assessment and resilience (December 2018)
4.20) (Mantovani A) Chemistry focus: Uncertainties, a current hotspot in the risk analysis of toxicants (April 2019)
4.21) (Frazzoli C, Mantovani A) Combining a bottom-up movement: endocrine disruptors and non-communicable diseases in Africa (July 2019)
4.22) (Mantovani A, Baldi F) Climate changes: modifying our views on environmental risks (October 2019)
4.23) (Mantovani A) Health and environmental risks of the near future (October 2019)
4.24) (Mantovani A) Pesticide risk assessment: European framework shows need for safer alternatives (December 2019)
4.25) (Mantovani A.) Contaminants and infections: a link to explore (April 2020)
4.26) (Mantovani A.) Vitamin A joins endocrine disruption (June 2020).

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PERSONAL INFORMATION

Jose V. Tarazona Lafarga

Carretera de Majadahonda a Pozuelo km 2.200, 28220 Majadahonda, Madrid, Spain

+34 91 822 3876 +34 676 848915

jtarazona@isciii.es; jvtparc@gmail.com

Sex Male | Date of birth 11/05/1959 | Nationality Spanish

WORK EXPERIENCE

October 2022 – Now

Research Professor on Environmental Health Risk Assessment Science

Spanish National Environmental Health Centre, Instituto de Salud Carlos III, Ministry of Science and Innovation, Majadahonda, Madrid, Spain. www.isciii.es

- Research Professor at the Spanish National Health Institute, responsible for creating a new unit on risk assessment for the National Environmental Health Centre. Involved in the EU research partnership PARC, I am collaborating in several activities and leading a project under Task 6.4.4., entitled "Quantify effects of PPP and other stressors through landscape risk assessment informing on environmental impacts" for developing landscape based risk assessment methods for pesticides.

Business or sector Public research institution, top academic position in a national research institute.

May 2019 – September 2022

Senior Scientific Officer, Scientific Committee and Emerging Risk Unit

European Food Safety Authority, Parma, Italy. www.efsa.europa.eu

- Senior scientist of the unit responsible for the coordination of EFSA's Scientific Committee and crosscutting methodological developments. I coordinated several SC Working Groups and chaired the Scientific Committee WG on Nanotechnology and the EFSA Nanonetwork. In addition, I was responsible for developing and coordinating three large projects related to the use of New Approach Methodologies for chemical risk assessments, covering different EFSA related areas: pesticides, novel foods, food and feed additives, food contaminants and nanomaterials.

Business or sector European institutions, senior scientist position in an EU Agency

October 2013 – April 2019

Head Pesticides Unit

European Food Safety Authority, Parma, Italy. www.efsa.europa.eu

- Head of the largest scientific unit in EFSA, producing 20-25% of all EFSA scientific outputs. The Unit was responsible for the risk assessment of pesticides (dietary, occupational and environmental), provided support to the PPR Panel and two EFSA networks, conducted the peer-review of active substances and the risk assessments related to the MRL setting, organised the annual pesticides monitoring programme and published the Annual Report on Pesticides Monitoring, the annual scientific report for supporting the EU CODEX position, and complementary activities in the field of pesticides allocated to EFSA. The Unit also contributed to horizontal and international activities and led several aspects of the EFSA 2020 Strategy.
- In 2019 the Unit was divided in two smaller units, I was appointed as Head of the Pesticide Residues Unit

Business or sector European institutions, manager position in an EU Agency

January 2012 - October 2013

Scientific Chair Evaluation

European Chemicals Agency, Helsinki, Finland. www.echa.europa.eu

- Chair of the ECHA Scientific Platform for Environment and Exposure, responsible for ECHA-wide cross-directorate scientific assessments related to REACH, CLP and biocides, and the organisation of ECHA Topical Scientific Workshops on environmental issues.
- Scientific Chair in the Evaluation Directorate; covering the following tasks: Contribute to develop new and on-going strategic scientific issues and activities in support of the EU legislative framework on chemicals. Provide senior expert advice and assistance to REACH guidance development and other crosscutting tasks in the area of environmental toxicology. Contribute to the development of a concept for a systematic scientific training and development plan for ECHA and to the Graduate Program for training future risk assessors. Contribution to the principles and practices of contacts with scientific organisations.

Business or sector European institutions, senior scientific adviser in an EU Agency

August 2009 – January 2012

Chair of the Committee for Risk Assessment

European Chemicals Agency, Helsinki, Finland. www.echa.europa.eu

- Chair the ECHA's Committee for Risk Assessment (RAC), composed by around 40 experts nominated by Member States and supported by advisers and invited experts. RAC is the ECHA body responsible for setting the Agency's opinions on issues related to risks for human health and the environment. During the starting phase of the Committee (up to December 2010) the main duty was to steer the development of the Committee's working practices. After the Committee's consolidation, the main needs were linked to streamline the processes, ensuring the Committee readiness for affording the exponential growth in its workload, but keeping a top scientific level in all the opinions. To coordinate the RAC activities with those from scientific bodies advising other EU institutions in risk assessment, including EFSA, SCOEL, DG SANCO Scientific Committees, etc. This activity included the early identification and solving of scientific divergences in the opinions and the general cooperation for coordination, exchange of risk assessment methodology, etc. Support to other ECHA scientific, communication and dissemination activities, including the Task Force on Nanotechnology.

Business or sector European institutions, senior scientific adviser in an EU Agency

September 2006 – December 2008

Scientific Director, Spanish REACH Reference Centre

Functional structure of the Spanish National Institute for Agricultural and Food Research and Technology and the University of Alcala, created under the initiative and sponsorship of the Spanish Ministry of the Environment

- As overall responsible of the Contract Agreement and Project leader I was responsible for the establishment and scientific direction of the REACH Reference Centre, providing support to the Spanish CA for setting up the starting phase of the REACH Regulation and to the industrial sector on REACH and CLP issues as the Spanish REACH helpdesk. The Centre was responsible for giving technical support to the Spanish CA, creating awareness on REACH and CLP, produce practical guidance, conduct training activities, and engage with the industrial sector conducting Pilot Projects on the implementation of both regulations.

Business or sector National regulatory advisory body, senior manager position in an a functional public funded structure

November 1992 – August 2009

Head Division of Ecotoxicology and Environmental Risk Assessment

Spanish National Institute for Agricultural and Food Research and Technology. Madrid, Spain, www.inia.es

- Head of the Division of Environmental Toxicology at CISA-INIA, and then Division of Ecotoxicology and Environmental Risk Assessment, at the Department of the Environment I was head of the unit responsible for the ecotoxicological and environmental risk assessment, leading the group and ensuring top quality achievements and international reputation, as well as competiveness as research group at EU and international level. The division provided direct scientific support to the Spanish Government regarding chemicals risk assessments in the area of new and existing chemicals, REACH, CLP, biocides, pesticides, veterinary pharmaceuticals, soil and water pollution, industrial emissions and waste management, through a set of research contracts. One of this research contracts included the establishment and scientific direction of the REACH Reference Centre.

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Business or sector National public research institutions, manager position in an a public organisation

July 2001 – January 2008

Director, Department of the Environment

Spanish National Institute for Agricultural and Food Research and Technology. Madrid, Spain, www.inia.es

- With the creation of the Department of the Environment I was appointed its Director, and re-elected for the maximum allowable period. As Department director I was responsible for the strategic planning of the Department during the start-up and consolidation phases. The responsibilities of the Department Director included the daily management of the Department activities, setting the annual programme and coordinating the long-term planning of the Department's development, chairing the Department's Council, identification of needs in human resources and equipment, budget control and distribution of the resources, reporting, staff management, institutional relationships, dissemination and communication policy, etc.

Business or sector National public research institutions, senior manager position in an a public organisation

October 1982 – August 2009

Scientific Researcher

Spanish National Institute for Agricultural and Food Research and Technology. Madrid, Spain, www.inia.es

- Scientific research in toxicology, ecotoxicology and risk assessment including, environmental protection and environmental monitoring, the environmental assessment of chemicals, including pesticides, biocides and veterinary medicines was one of the main research lines. Permanent INIA staff since 1982, after my PhD in 1986, I completed my postdoctoral training with three one-month periods at the Universities of Uppsala (Sweden) and Herriot-Wat (Edinburgh, UK) and at INRA (France), complemented with a set of short visits to several European and US research institutions, and established my own research group. My initial research field was veterinary toxicology, and was expanded to the assessment of environmental contaminants and ecotoxicology, aquatic and terrestrial, including environmental (bio)monitoring, field assessment, development of new testing methods (from in vitro techniques to higher tier multispecies toxicity testing, etc. Since 1992 my research interest was further expanded to exposure assessment, modelling and risk assessment.
- In addition to my research activity since 1992 I was involved in the scientific advisory bodies of the European Commission and several EU Agencies, OECD, and several UN institutions, chairing international experts groups on the GHS for the OECD and UN.

Business or sector National public research institutions, permanent researcher in an a public organisation

January 1982 – June 1986

Assistant Professor of Toxicology

Veterinary Faculty of Madrid, Universidad Complutense, Madrid, Spain

- Teaching and research activities in the area of mammalian, human and veterinary toxicology.

Business or sector Higher Education institution, assistant professor at a public university

EDUCATION AND TRAINING

January 1982 – July 1986

PhD in Veterinary Sciences (Toxicology)

University Complutense, Madrid, Spain

October 1976 – July 1981

Doctor in Veterinary Medicine

University Complutense, Madrid, Spain

PERSONAL SKILLS

Mother tongue(s): Spanish

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	Proficient user	Proficient user	Proficient user	Proficient user	Proficient user
Italian/French	Basic user	Basic user	Basic user	Basic user	Basic user

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user
Common European Framework of Reference for Languages

Organisational / managerial skills

- I have acquired strategic leadership and organisational skills through a number of involvements at national and European level.

Technical knowledge

- Good knowledge of the European horizontal and vertical chemicals legislations, with direct involvement in the transition from the previous to the actual regulatory frames covering REACH, CLP, biocides, pesticides and the links with international conventions.
- Consolidated expertise and international recognition in human health and environmental protection, chemicals risk assessment and management, REACH-IT, IUCLID, project and data management tools, modelling, etc, covering national, European and international contexts.
- Very clear understanding of the European institutions system acquired through over 30 years of interaction with different European institutions including several Commission DGs, several European Agencies, the European Parliament and the Council.

Communication skills

- Proven experience in international negotiations acquired as member and head of delegation (national and European delegations) and chair of technical and regulatory expert groups and international networks

Digital competence

SELF-ASSESSMENT				
Information processing	Communication	Content creation	Safety	Problem solving
Proficient user	Independent user	Proficient user	Basic user	Independent user

Levels: Basic user - Independent user - Proficient user
Digital competences - Self-assessment grid

Replace with name of ICT-certificate(s)

ADDITIONAL INFORMATION

Memberships in multinational scientific committees on chemicals risk assessment

European Commission Scientific Committees:

- Member of the Scientific Committee on Toxicity and the Environment CSTE (1992-1997),
- Member of the Scientific Committee on Toxicology, Ecotoxicology and the Environment CSTEE (1997-2004),
- Member of the Scientific Committee on Health and Environmental Risks SCHER (2004-2013),

- Vice-chair CSTEE and SCHER (2000-2009) and member DG SANCO Inter-Committees Coordination Group (2004-2009).
- Chair of ERA-WG EU-Task-Force Harmonization of Risk Assessment (2001-2003).
- Invited Expert Scientific Committee on Plants
- Invited Expert Scientific Committee on Animal Feed
- Focal point for the Water Framework Directive.
- Advisor for the EU Environment and Health Strategy.
- Joint Research Centre-ECB Technical Committee on Classification & Labelling (1995-2006),
- Joint Research Centre-ECB Technical Meeting on Existing Chemicals (1996-2006),
- Joint Research Centre-ECB Technical Meeting on Biocides (2004-2009).

EU Agencies:

- Member of the Risk Assessment Committee ECHA-RAC (2007-2009),
- Invited expert EFSA FEEDAP Scientific Panel
- Invited expert EFSA PPR Scientific Panel
- Invited expert for EMA and EEA activities.

Global Institutions:

- Member UN-POP Review Committee (2005-2008)
- Expert of the UN-Global Harmonisation System Sub-Committee
- UN and WHO consultant for Latin America
- OECD Expert involved in several OECD programmes (guidelines, agri-environment indicators, hazard and risk assessment, SIDS)
- Chair OECD-Expert-Groups GHS-Aquatic-Hazards (2004-2006)
- Chair GHS-Terrestrial-Hazards (2003-2008)
- EFSA contact point for APCRA (2016-2022)
- Member OECD WP Nanomaterials (2021-2022)
- Member Canadian Chemicals Management Plan Science Committee (2021)
- Co-chair of the WG on NAMs at ILMERAC (2021-now)

Publications

- Author/editor of 24 books and monographs, including the Reference Book: Encyclopedia of Toxicology, 3rd edition, Elsevier: four volumes with 5220 Pages.
- Author of over 300 scientific publications and several book chapters.
- (Co)author as member or invited expert of hundreds of scientific opinions from CSTE, CSTEE, SCHER, SC Plants, SC Animal Feed, EFSA-FEEDAP, EFSA-PPR, ECHA-RAC, UN-POPRC, and EFSA Scientific Committee.

Honours and awards

Encomienda de la Orden del Mérito Agrario (Spanish Civil Order Distinction)
Full Member of the Royal Academy of Veterinary Sciences, Instituto de España, Spain

Signed confidentiality agreements of IVC2023 members

Signed confidentiality agreements of IVC2023 members

ctgb

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 from FERA, Department for Environment, Food and Rural Affairs, UK

In the position of: Science 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)

HINDHEAD, UK 24th January 2023
(town/city in which signed, date of signature)

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): ANTIO SARI PÄIVIKKI

Date and place of birth: 31.08.1961 RAAHE, FINLAND

Working for: the Finnish Safety and Chemicals Agency

In the position of: Senior Officer

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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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)

Kanjaa, Finland 20.1.2023
(town/city in which signed, date of signature)

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names) MIČOVIĆ ELIZABETA

Date and place of birth 09.09.1960

Working for: UNIVERSITY OF MARIBOR, FACULTY OF AGRICULTURE AND LIFE SCIENCES

In the position of: ASSISTANT PROFESSOR

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)

LJUBLJANA, 20.1.2023
(town/city in which signed, date of signature)

ctgb

Declaration of confidentiality provided by third parties

The undersigned
(surname, followed by first names): MANTOVANI ALBERTO

Date and place of birth: 22/02/1956 BOLOGNA (ITALY)

Working for: ISTITUTO SUPERIORE DI SANITÀ (RETIRED AFTER 28/02/2023)

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.

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)

ROMA 20/01/2023
(town/city in which signed, date of signature)

Declaration of confidentiality provided by third parties

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

Date and place of birth: 11 MAY 1959, BARBASTRO, SPAIN

Working for: INSTITUTO DE SALUD CARLOS III

In the position of: RESEARCH PROFESSOR

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.

TARAZONA LAFARGA JOSE VICENTE - 51881455X

Firmado digitalmente por TARAZONA LAFARGA JOSE VICENTE - 51881455X
Fecha: 2023.01.20 11:24:43 +01'00'

(Signature)

MADRID, 20/1/2023
(town/city in which signed, date of signature)

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Signed Declaration of interests IVC members

Signed Declaration of interests IVC members

DECLARATION OF INTEREST
IVC 2023

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.

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DECLARATION OF INTEREST
IVC 2023

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?

☐ 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
I was a member of the previous IVC 5 years ago appointed by Ctgb for my professional knowledge and expertise in this area	IVC2018	Me	

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

☐ Yes..... ☑ No

If yes, please provide details below

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

A.C. Hardy — Name

Signature

24 January 2023 — Date

ctgb

DECLARATION OF INTEREST
IVC 2023

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?

☐ 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	Sari Autio	20.1.2023
Name	Signature	Date

ctgb

DECLARATION OF INTEREST
IVC 2023

Declaration

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If yes, please provide details below

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ELIZABETA MIĆOVIĆ	Mićović	20.1.2023
Name	Signature	Date

ctgb

DECLARATION OF INTEREST
IVC 2023

Declaration

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☐ Yes……**X 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

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If yes, please provide details below

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Alberto Mantovani		20/01/2023
Name	Signature	Date

ctgb

DECLARATION OF INTEREST
IVC 2023

Declaration

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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.

Jose V Tarazona	TARAZONA LAFARGA JOSE VICENTE - 51881455X	20/01/2023
Name	Signature	Date

ctgb

Action Plan for IVC2023

Action Plan for IVC2023

Action Plan for the 3rd International Visitation Committee, 2023 (IVC2023)

1. At the request of the Ctgb Board, the 3rd International Visitation Committee (IVC2023) was established by Dr Tony Hardy and endorsed by the Board to start on 1st January 2023. The members of the IVC2023 are:

    I. Dr Anthony Hardy, UK, retired, former independent expert with the European Food Safety Authority (Chair)
    II. Dr Sari Autio, Finland, Finnish Safety and Chemicals Agency Tukes
    III. Dr Alberto Mantovani, Italy, Istituto Superiore di Sanità (ISS)
    IV. Dr Elizabeta Mičović, Slovenija, University of Maribor
    V. Professor José Tarazona, Spain, Spanish National Environmental Health Centre. Instituto de Salud Carlos III (ISCIII)

    The preliminary meeting of the IVC was held online on 8th February 2023.

2. The IVC2023 was requested to address the following areas:
    - The scientific quality and legal compliance of the decisions on authorisation of plant protection products and biocides. In particular:
        - Quality: the overall scientific and technical quality of the risk assessment documents that are prepared by the secretariat to substantiate the subsequent formal decisions by the Board.
        - Also the legal compliance of the evaluations, e.g. are they based on the applicable guidance documents?
        - 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.
          Also the legal compliance of the process, e.g. is it based on the applicable guidance documents? Compliance with legal deadlines?
        - Board: the contribution and role of the Board in the decision- making process, in particular the level of competence and procedural aspects.
        - Existing authorizations and possible actualization with a view to developments in EU legislation (article 56, (EC) No 1107/2009; article 48, (EU) 528/2012)
        - Progression in new scientific developments.

    - Dealing with demands of all stakeholders (European Commission, ECHA, EFSA, Competent Authorities of other Member States, industry, general public) and apparently contradictory requirements, considering:
        - The requirements, procedure and timeframes for product authorisation as set out in the biocides ((EU) 528/2012) and the plant protection products regulation ((EC) No 1107/2009);
        - The need for transparency and the existing rules for disclosure;
        - 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.
        - 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.

        - The legal timelines as laid down in the biocides and plant protection products regulations are not met by the Member States. Current practice and theory behind the legal timelines at the time of implementation of the regulations is diverging more and more.
        - The role and contribution of Competent Authorities with regard to the European Green Deal, Farm-to-Fork strategy, EU Chemicals Strategy, National strategies, knowing that Competent Authorities are responsible for decisions on the **authorisation**, while the European and national strategies contribute to a reduction of the **use** of products.

Evaluation of the Scientific Process

3. This will involve:
    a. Evaluation of the availability and accessibility of the documentation provided;
    b. Identification of gaps in the descriptions of the scientific process;
    c. Assessment of the practical use and adherence to the documentation covering the scientific process;
    d. In-depth evaluation through the application of a series of quality indicators as described below.
    e. Examination of the legal compliance with international requirements.

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 aspects will be considered:

    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 and exchange such as lectures at scientific symposia, congresses, *etc.*, scientific publications, guidance documents, rebuttals, *etc.,* against the quality indicators developed.

    Evaluation of the selected outputs will be done by the individual members of the IVC2023, 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

5. 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

6. A series of semi-quantitative quality indicators were 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. For consistency and comparability, the IVC2023 will apply the same approach. The indicators agreed upon are as follows:

6.1 **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 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.

6.2 **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, both internal and external, 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 IVC2023 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 IVC2023 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.

6.3 **Indicators of the quality of the Board's Decision-making process**

a. The extent to which the profiles of individual members and of the Board as a whole fits 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.

6.4 **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.

6.5 **Indicators of success in fostering sustainable pest management**

a. Degree of success of the Dutch national action plan on the sustainable use of pesticides (2018-2023).
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 since 2018 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

7. To facilitate the work of the IVC2023, 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 IVC2023 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

8. 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:

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

a. A document detailing the response of the Ctgb management and Board to the 11 individual recommendations made by the IVC2018 in their report and a summary of the progress made since 2018 in these specific areas.
b. Inventory of and access to all technical, procedural and guidance documents relating to the scientific process that are currently in use – those introduced since 2018 to be identified.
c. Inventory of and access to legal documents relevant for the work of the Ctgb – those introduced or amended since 2018 to be identified.
d. 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 2018 to be identified.
e. Detailed organisational chart of scientific staff and management – changes since 2018 to be highlighted.
f. CVs, descriptions of functions and responsibilities, including identification of critical functions of all staff and Board Members.
g. Access to Declarations of Interest (DOI) of all scientific staff over the last 4 years.
h. Access to reports/documentation on internal and external scientific peer review processes and evaluations.

i. Access to documentation on procedures for dealing with formal complaints by dossier owner(s) and interested third parties and records of how these complaints have been addressed, including the history (4 years) of formal appeals.
j. Access to written communications with applicants.
k. Access to documentation on Mutual Agreement (MR) procedures.
l. A list of plant protection DARs, Biocide CARs and product authorizations granted since January 2018, together with details of the identity (ISO Common names) and content of the active substances they contain and in the case of product authorisations:-
    a. the formulation types (GIFAP Code);
    b. an indication to identify those for which the Ctgb conducted a zonal evaluation
    c. an indication to identify those for which another Member State conducted the zonal evaluation relied upon,
    d. 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
m. 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 IVC2023 were considered.
n. Access to operations manuals and SOPs prepared for use by scientific staff and dossier managers (co-ordinators) – those introduced since 2018 to be identified (to the extent not included in item a).
o. Access to policy and operational guidance prepared for Board members in making management Decisions on proposals submitted – those introduced since 2018 to be identified.

The list of requested items will be submitted to the Ctgb secretariat by the end of 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 IVC2023 during the course of its work.

Caveat with respect to requested documentation

10. It should be clear that, whereas the 3rd IVC considers the above-mentioned requests relevant for carrying out is evaluation, it is aware that many of the available documents addressing some, or all, the requests listed above may not available in English and that time and budget do not allow for the translation of a substantial number of documents into English. Consequently, the 3rd IVC is willing to focus primarily on documents (in English) that the Ctgb management and Board would consider of importance for the work of the ICV in the present context. Any suggestions in this respect would be highly appreciated.

Interviews

11. 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 24th and 25th 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. The Committee also wishes to

speak with the Board members. Provisionally 22nd March is earmarked for these interviews (see also under Time Schedule).

Time Schedule

12. The following time schedule was agreed between the Ctgb Board, the Ctgb management and the IVC2023:

    a. January 2023: Agreement on Terms of Reference (ToR) and of the members of the committee.

    b. 8th February 2023: Online **Preliminary meeting** of the international visitation committee to discuss the Action Plan, strategy, tasks and timing.

    c. Mid-February 2023: 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. 22nd February 2023: **Approva**l of the Action Plan by the Board.

    e. 22nd March 2023 **Second meeting** of the IVC2023 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.

    f. End March 2023: The final list of questions from the IVC2023 to be forwarded to the Secretariat.

    g. March 2023: 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.

    h. Mid-April 2023: online **meeting** of the IVC2023 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.

    i. End of April 2023: 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 documentation generated by the Board in decision-making.

    j. End of April 2023: As appropriate, a **face-to-face or virtual meeting** of the IVC2023, including a session as needed, with the Board and, with the senior Ctgb management and / or external individuals. The selection of external experts for consultation with outside organisations will be done with the consent of the Ctgb Director and Chairman of the Board, as appropriate.

    The meetings in late 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.

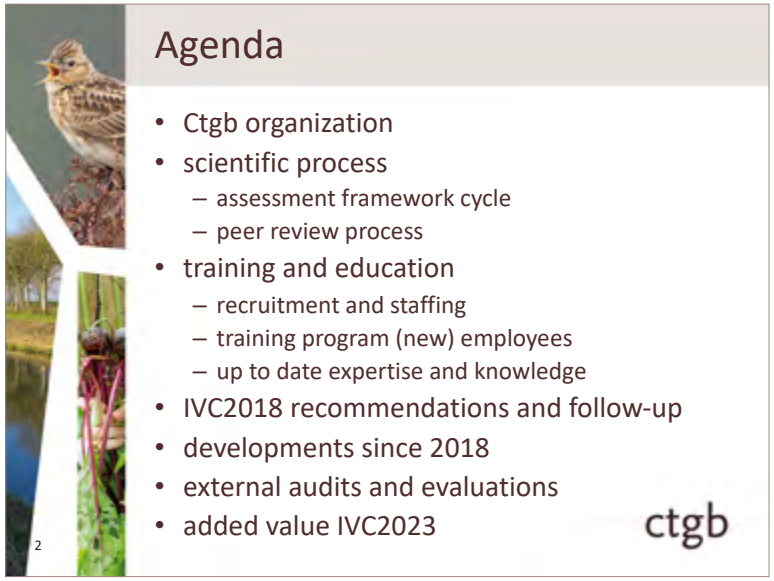
    k. 24th and 25th May 2023: a 2-day **visitation** at the Ctgb.

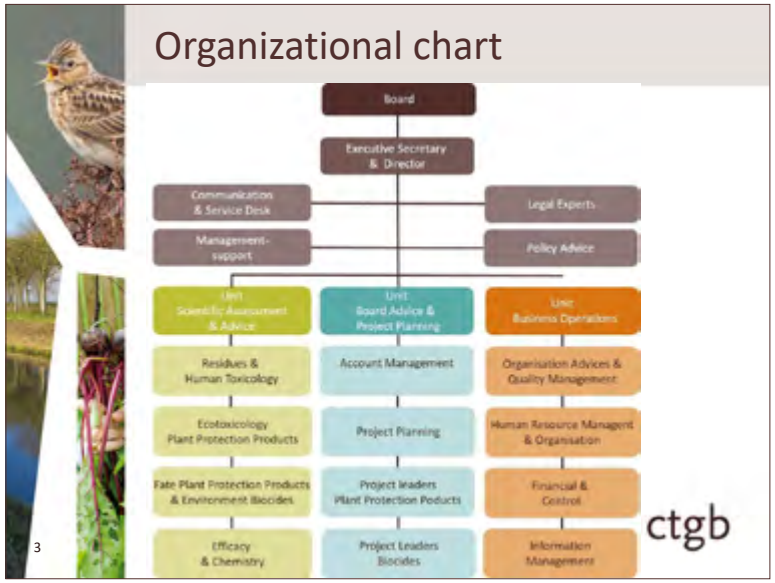
    l. End of August 2023: **submission** (possibly by electronic mail) to the Ctgb Board and senior management of the draft final report of the visitation mission which is likely to be a concise report with annexes.

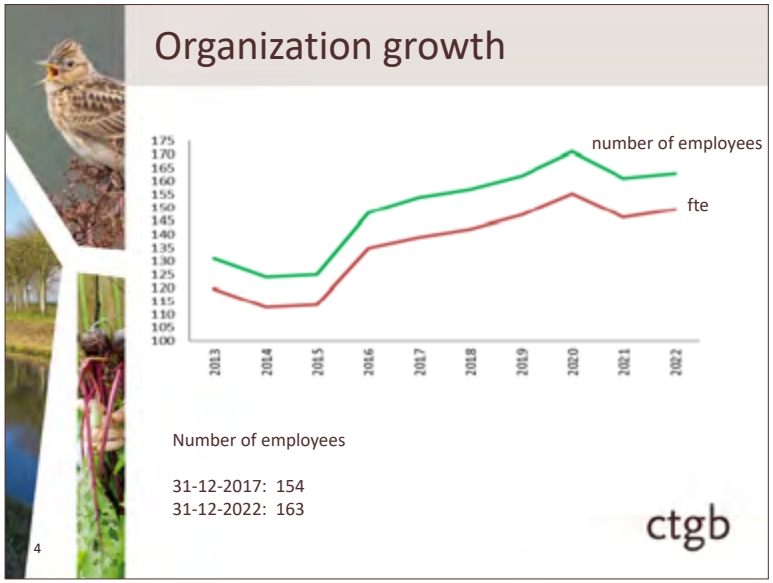
    m. 27th September 2023 **Formal presentation of the final report** to the Board and senior staff by the Chairman of the IVC supported by other team members. Possibly, a press statement or press meeting may be appropriate (to be decided by the Ctgb).

Powerpoint presentations by Ctgb Management (22nd March 2023 and 24th May 2023)


Kick-off meeting IVC2023 with
Board and management team
Ingrid Becks
executive secretary / director
22 March 2023
ctgb


Agenda
• Ctgb organization
• scientific process
– assessment framework cycle
– peer review process
• training and education
– recruitment and staffing
– training program (new) employees
– up to date expertise and knowledge
• IVC2018 recommendations and follow-up
• developments since 2018
• external audits and evaluations
• added value IVC2023
ctgb
2


Organizational chart
Board
Executive Secretary & Director
Communication & Service Desk
Management-support
Legal Experts
Policy Advice
Unit Scientific Assessment & Advice
Unit Board Advice & Project Planning
Unit Business Operations
Residues & Human Toxicology
Account Management
Organisation Advices & Quality Management
Ecotoxicology Plant Protection Products
Project Planning
Human Resource Management & Organisation
Fate Plant Protection Products & Environment Biocides
Project leaders Plant Protection Products
Financial & Control
Efficacy & Chemistry
Project Leaders Biocides
Information Management
ctgb
3


Organization growth
number of employees
fte
175
170
165
160
155
150
145
140
135
130
125
120
115
110
105
100
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
Number of employees
31-12-2017: 154
31-12-2022: 163
ctgb
4

Outline authorisation process

meeting applicant to improve quality dossier

use of guidances and jobaids

Pre-application → Intake → Assessment → Decision → Post-approval

define assessment framework

peer review of assessment

Ensure effective recruitment, training and continuous learning

ctgb

5

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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6

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 phase

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7

Training & education

- 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).
- New: for ecotoxicologists we engaged with SETAC for certification. Currently, 8 ecotoxicologists are certified and 4 others are following the procedure to become certified.

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8

Training & education

Training process new employees

- Learning on the job in a mentoring system
- Introduction day
- Full training requires up to one year

First interview (manager/employee): existing knowledge, required personal development → General and personal development programme → 3-4 months → Evaluation interview (manager/employee): existing knowledge, reuired personal development

Training process experienced employees

- Annual review with each employee to evaluate progress, educational wishes/needs, competencies, workload, and development actions

ctgb

9

Training & education

Up to date expertise and knowledge

- participating and presenting in internal and external (EU) workshops, conferences or courses
- workshops in the field to experience daily practice
- Participating in guidance development:
  - ➢ methodology **development** by strategic partners like RIVM and WUR
  - ➢ review and applicability check by Ctgb
- occasionally contribute to scientific publications (but no primary goal)

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10

IVC2018 recommendations – follow-up

- 11 recommendations, in 3 categories:
  - – Board and Management
  - – Openness and transparency
  - – Scientific output and outreach
- Ctgb Action Plan in 2018
- March 2023: Ctgb prepared document with follow-up and progress made

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11

IVC2018 recommendations – follow -up

Highlights:

- interactions between Board members and scientific assessors further strengthened
- regular updates CV's and Declaration of Interest of employees and Board members. CV's and DoI's of the Board and director published on Ctgb website
- certification ecotoxicologists
- more clear distinction between risk assessment and risk management (PPP) and more transparent on this
- extensive 'OBSO' program to renew IT application landscape (organization-wide collaboration platform): DMS, CRM, case management, PowerBI, intranet, applicant portal

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12

Developments since 2018

Important themes:

- timelines
  - too long, problem for many years already, EU-wide issue, Brexit increased problem
  - measures taken, not sufficient
  - increasing complexity and size of dossiers
  - organizational changes, implementation Oct. 2023: more balance between scientific quality, time and costs (devil's triangle), strengthening process chain, reducing backlog, working in dedicated multidisciplinary teams (matrix organization), application portfolio divided into smaller pieces
  - backlog legal procedures reduced to zero!

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Developments since 2018

Important themes:

- capacity
  - disbalance between expertises
  - scarcity in labour market
  - impact renewal assessment glyphosate
  - training new employees
- corona
  - suddenly working at home for 100%
  - crisis management
  - a lot of extra work (hand disinfection)
  - no conferences, training, field trips possible
  - finding new balance working at home and at Ctgb
  - impact hybrid way of working on commitment of staff to organization and each other?

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Developments since 2018

Important themes:

- sustainability
  - EU and national strategies
  - Ctgb frontrunner knowledge and experience; large contribution to e.g. new data requirements for micro-organisms
  - Ctgb relatively 'green' portfolio of applications (PPP); green team
  - draft sustainable use regulation

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Developments since 2018

Important themes:

- new Ctgb strategy 2024-2027:
  - We commit ourselves to reduction of the lead times of applications
  - We facilitate the sustainability of the active substance and products package
  - We contribute to a better insight in the long term health effects of plant protection products and biocides

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External audits and evaluations
ISO 9001:2015
CIIO
• Ctgb is ISO certified. Annual external audit with focus on *quality management, plan-do-act cycle* (learning organisation)
• Based on national law once every 5 years evaluation of *effectiveness and efficacy*. In 2021/2022 performed by AEF (consultant)
• Once every 5 years IVC visitation with focus on *scientific and legal quality* of the Ctgb decisions and underlying assessments.
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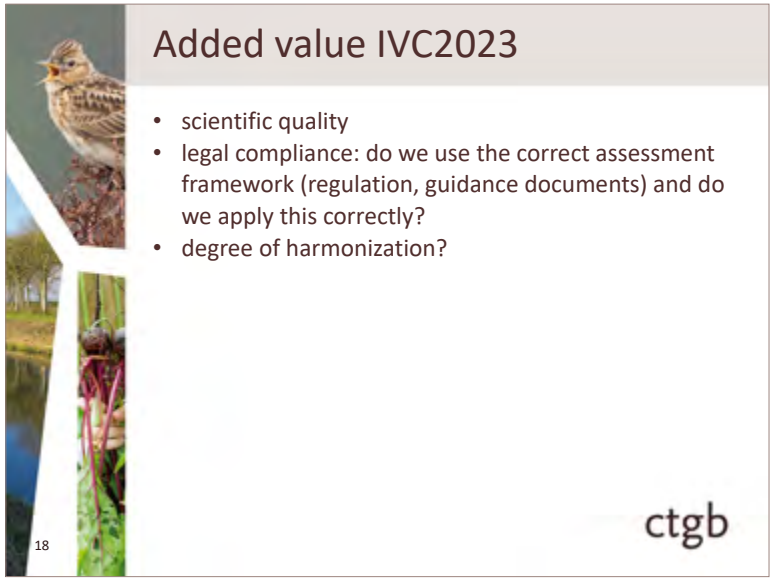
Added value IVC2023
• scientific quality
• legal compliance: do we use the correct assessment framework (regulation, guidance documents) and do we apply this correctly?
• degree of harmonization?
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Current developments at Ctgb
Presentation for IVC2023
Ingrid Becks, executive secretary / director
Nicole van Straten, deputy executive secretary / director and manager department scientific assessment and advice
24 May 2023
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Content
• Ctgb multi annual strategy 2024-2027
In order to be able to reach the strategic goals:
– organizational changes in 2023
– renew IT application landscape
2
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Ctgb multi annual strategy 2024-2027
Process:
• Evaluation current strategy
• Taking into account results external ISO audits, internal audits, IVC, external evaluation with regard to effectiveness and efficiency
• External analyses, a.o. stakeholder research
• Internal analyses, a.o. staff research
• Strategic sessions with management and board
• Strategic sessions with responsible ministries
• Round-the-table discussion with stakeholders
3
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Ctgb multi annual strategy 2024-2027
• We commit ourselves to reduction of the lead times of applications
• We facilitate the sustainability of the active substance and products package
• We contribute to a better insight in the long term health effects of plant protection products and biocides
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Timelines

- too long
- problem for many years already, for PPP and biocides
- EU-wide issue (competent authorities, European Commission, EFSA, ECHA)
- Brexit increased problem
- increasing complexity and size of dossiers
- no easy solution
- responsible ministries are going to help us at European (political) level: discussion on issues we face as competent authority

- Ctgb backlog legal procedures reduced to zero

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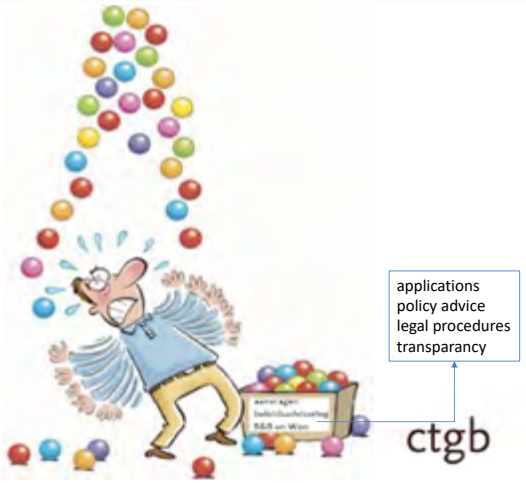
Current situation



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Current situation

What we need to do:
Besides keeping the quality of our work at a high level, create solutions within our sphere of influence to reduce timelines and limit costs (where possible) for the applicants.

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Goals organizational changes

- more balance between scientific quality, time and costs (devils triangle)
- strengthening process chain

Results:
- reducing backlog
- reducing timelines
- limit application costs where possible
- responsibilities lower in the organization

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Organizational changes, **what**?

What are we going to do:
- more focus on reducing timelines
  - management needs to steer the organization to finalize tasks/applications as efficiently as possible
  - more focus on project management in the process chain
  - taking risk management decisions
- finding, development and binding of staff
  - optimize recruitment of staff
  - create more career opportunities
- stimulate internal cooperation

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Organizational changes, **how**?

- creating 2 separate departments: PPP and biocides
- dividing all the work in manageable portfolios
- risk management where possible, to take work out of the 'system'
- making choices **not** to do tasks, if possible (e.g. participating in commenting rounds/peer review)
- strengthening project management in the process chain
- working in structural multidisciplinairy teams (MDT) with a manageable portfolio
- increasing efficiency and decisiveness
- strengthening cooperation (in the process chain)
- focus on finalizing tasks/applications
- creating senior positions for project managers, experts and legal advisors

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Current organizational chart

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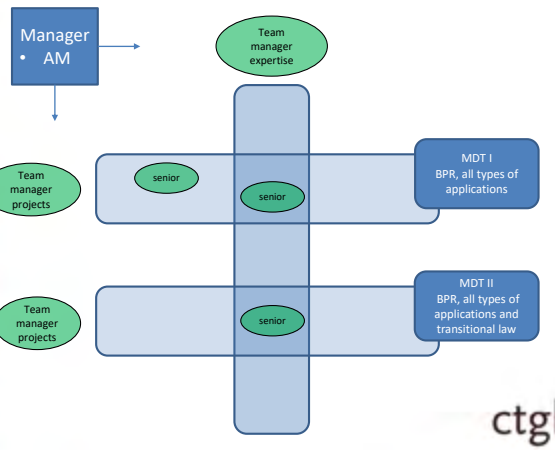
New: matrix organization biocides



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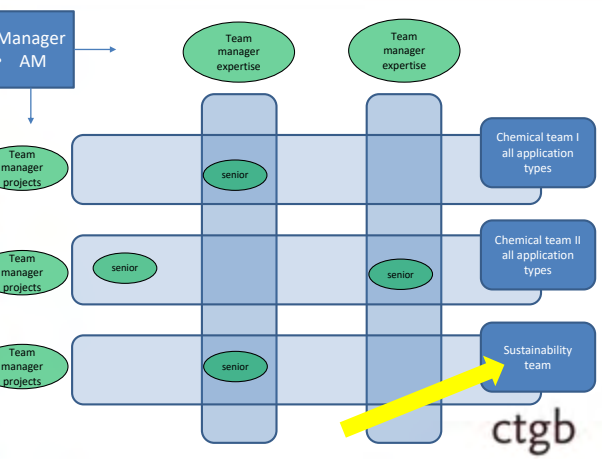
New: matrix organization PPP



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Renew IT application landscape

- extensive 'OBSO' (organization-wide collaboration platform) program:
  - case management (workflow)
  - DMS (document management system)
  - CRM (customer relationship management)
  - Intranet
  - Office 365 (working together in one document)
  - PowerBI (monitoring results/progress)
  - applicant portal

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Renew IT application landscape

Advantages:

- integrated landscape instead of individual tools (using one platform as much as possible)
- modern technology
- supporting our staff as much as possible
- user friendly, increased safety of data
- complete support of workflow
- less administrative burden (less double input), increased data quality
- better search tool
- more visual and real time monitoring
- applicants can see the status of their application

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Developments since the IVC visitation in 2018

Developments since the IVC visitation in 2018

Developments since the IVC visitation in 2018

(Ctgb July 2023)

On request of the Ctgb, a second visitation has been performed from January – August 2018, by an International Visitation Committee (IVC).
The 2018 IVC report, with a number of recommendations, has been sent to the House of Representatives by the Minister of Agriculture, Nature and Food Quality in November 2018, accompanied by the Ctgb Action Plan as follow-up of the recommendations.

The IVC has done 11 recommendations, categorized in 3 subjects:

1) Board and Management
2) Openness and transparency
3) Scientific output and outreach

In the table below the Ctgb Action Plan of 2018 is presented in the left column. In the right column the current state of play is given.

Furthermore, this document also contains an overview of highlights since 2018, that have impacted Ctgb to a more or lesser extent.
This information can be found after the table.

Action plan sent to the Minister of Agriculture, Nature and Food Quality (LNV) with the response of Ctgb on the recommendations of the IVC2018 (dd October 2018) Text *in italic* has been translated from Dutch to English with Google translate	**Update of follow-up and progress made to the IVC2018 recommendations (dd March 2023)**
Ctgb Action Plan in response to the 2018 International Visitation Committee report ***Introduction*** *At the moment the Ctgb is the only European authorisation authority to have set up an International Visitation Committee (IVC). The first visitation took place in 2013, and the Ctgb was reassessed in 2018. The international visitation committee (IVC) organized its work in complete independence, had access to all documents and held discussions with the Ctgb Board, management and employees from various teams. The chairman of the IVC has been approached by the Board. The chairman has nominated four members to the Board who have been appointed by the Board. The IVC has established its own working method and 'assessment criteria'. Composition and working method are described and explained in the report. The IVC has worked*	
very carefully and has scrutinized the organization in a tenacious and structured manner. Partly because of this, the report is of great value to the Ctgb. Not only because of the (positive) assessment of the quality of our decisions, but also because of the recommendations. Thanks to the broad orientation of the IVC and the thorough approach, the recommendations are relevant and give rise to further improvement of the working method and the functioning of the organization. *It is indicated below how the Ctgb will deal with the recommendations.*	
Recommendations IVC	
1. 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. **Response Ctgb:** *The Ctgb agrees well with the role of the Board as the figurehead of the organisation. Interaction between Board and secretariat has been actively improved in recent years. For example, there are annual "speed dates" between the secretariat and the Board and an hour is set aside each month for a theme session before the start of the Board meeting. This is a session in which the Board is updated on certain themes. These sessions are provided by secretariat experts and are followed by an informal lunch. The evaluation of the Board itself, carried out in 2018, shows that the Board sees a lot of progress on this point, but that the Board and secretariat still see room for improvement. For example, Board members will be more actively involved in the preparation of the theme sessions.*	**Update March 2023** The points as mentioned in the response have been implemented. The annual "speed dates" and theme sessions (followed by an informal lunch) before the start of the Board meetings are highly appreciated by the Board and the secretariat. Due to the covid situation and the long period of predominantly working from home (approximately March 2020 – March 20203), the "speed dates" have not taken place in 2020 and 2021. This was again possible and organized in 2022. During the covid situation all Board meetings have taken place, first via teleconference and later via videoconference. After a short pause, also the theme sessions have been continued during these years via videoconference (and later, when possible again, at the Ctgb office).. The active involvement of one or two Board members in the preparation of the theme sessions is indeed an improvement with regard to the cooperation between Board and secretariat and the precise content and scope of the theme session.
1a. 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. **Response Ctgb on recommendations IVC2018:** *As noted above, the interaction between the Board and employees will be further expanded. However, the basis for this interaction lies in the way in which the Board is informed, per dossier, about dilemmas, expert judgment and other relevant elements for the decision on admission or rejection. Major progress has been made on this point in recent years, and the system of 'cover notes' that has been introduced is a good medium for a procedure tailored to its purpose - good and well-reasoned decisions. In*	**Update March 2023** Interactions between Board members and the scientific assessors are further strengthened: • Scientific assessors contribute to and present thematic sessions for the Board. These sessions are now prepared in close collaboration with one or more Board members.

addition, Board members are more often involved one-on-one in thinking about more strategic, scientific issues.	• Scientific assessors reach out to a Board member for 1 on 1 discussions in case a (strategic) question in their field of expertise is raised. • On a case by case basis, scientific assessors are invited in Board meetings to explain specific scientific aspects or considerations for a dossier. • We keep improving our dossier cover notes upon feedback from the Board. • Speed dates between Board and scientific assessors (and others from the secretariat) were reinitiated after the corona pandemic. • Scientific assessors are invited to join during a Board working visit. • New Board members are trained by the scientific assessors
1b. 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. Organizing monthly so-called "brownback" lunches where one team shares its most interesting issues and experiences with colleagues in a very informal way could be a useful start. **Response Ctgb on recommendations IVC2018:** *The Ctgb does not agree with the comment that the HRM approach shows little interest in the personal development of employees. The incomplete CVs, which are not updated during service, and the "routine" approach to the "declarations of interest" do indeed need improvement, but rather are expressions of a focus on the people and less on the system. For example, the Ctgb pursues an active integrity policy, based on an "open and safe" atmosphere, as also noted by the IVC. The Ctgb certainly recognizes the value of a good system of CV administration, also to improve the (scientific) level of the employees and the Board. We also intend to review the system of declarations of interest. For the record: the secretariat consists of employees with a*	**Update March 2023** • HRM regularly (aim is annually) request an update of the CV's of employees and Board members. A CV template is used addressing appointment, knowledge, competences. • The CV's of the Board are published on the Ctgb website (Dutch pages) • HRM issues annually an update of the Declaration of Interest of employees and Board members. • The DoI's of the Board are published on the Ctgb website (Dutch pages ; English pages)

permanent contract and additional positions are not compatible with a position at the Ctgb, unless no conflict of interest can arise. *For a response to the current bonus system, see under 1c. The Ctgb supports the suggestion to organize low-threshold knowledge transfer sessions in a more structured way.*	• The importance of sharing issues and experiences among scientific assessors is recognized. As most issues focus on specific subjects rather than knowing each other's work, so called 'knowledge sessions' are organised. This is laid down in our internal communication policy. In this respect, knowledge sessions dealing with a.o. GLP, bee monitoring, pests, and Legionella took place. • Upon initiative of the scientific assessors for biocides a regular meeting between the different expertises working on biocides (in Dutch 'interaspectaal overleg') is held. This initiative has been followed by the scientific assessors for PPP's. Frequency of these meetings is ca. once every 4-6 weeks.
1c. 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. **Response Ctgb on recommendations IVC2018:** *The Ctgb adheres to the current government policy on rewarding employees. As the IVC, management also sees the disadvantages of the current individual-oriented "bonus system" in an organization that is pre-eminently based on teamwork. After all, many employees work on one file, not only the scientific assessors, but also project leaders and support staff. Individual rewards are not always appropriate. For this reason, the management, in consultation with the Works Council, has decided to abandon this system and switch to a system of "collective" remuneration.* *For individual employees, a stimulating package of tasks, participation in working groups and conferences and diversity of activities is a much more tailored 'reward system' for our type of organisation. The room that the organization offers its employees for broadening and training is also experienced by many employees as a form of a reward. Due attention will be paid to this.*	**Update March 2023** • We have made more budget available for team development and social bonding within the team. The team manager is responsible for the use of this budget. • An annual appraisal of the teams is carried out by the MT and the responsible team manager in which the teams are assessed on the basis of development and performance and whether they are fit for purpose for the coming year. On this occasion, or during the year when appropriate, the team manager can do a proposal for a team reward. This is the case if a special performance has been made due to extra tasks that have been performed or an important contribution to a project. • In addition to the regular salary grades, there is still the option of rewarding employees individually. An individual who develops quickly or performs above expectations can also be rewarded. This is also applied in practice by awarding them e.g. an extra increment in the next higher scale. The manager determines in cooperation with HRM who is nominated on what basis. Rewarding individuals also takes place during the year, at the appropriate moment. • Individual rewards can be awarded on a structural or incidental basis. Every year about 25 -30 people are nominated for such a reward. • At the end of 2022, Ctgb decided to switch to more job differentiation by adding senior positions to the job classification system. This concerns senior positions for scientific assessors, project leaders and legal advisors. These senior positions are classified at level 12. Senior positions are already being used within the other organizational units. These senior positions are not automatic career advancement positions based on knowledge and experience, but separate positions based on the core profile supplemented with additional tasks, responsibilities and competencies. Creating these positions gives employees the opportunity to grow. • Job differentiation will be implemented in light of the organizational change that will take place in October 2023.
1d. 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. **Response Ctgb on recommendations IVC2018:** *Although it has been Ctgb policy for years that the scientific assessors for human toxicology all have an ERT accreditation or follow a training course to obtain an ERT*	**Update March 2023** All human toxicologists are ERT or are being trained to obtain the ERT certificate.

accreditation, this is not yet the case for the scientific assessors for ecotoxicology. The existing ERT courses only had little added value for ecotoxicologists so far. *As the Ctgb understands, an Ecotoxicology certification was recently started at SETAC, of which the first students (from ECHA and EFSA, among others) were certified this year. The Ctgb will investigate whether this certification has added value for the scientific assessors of ecotoxicology and will participate in that case.*	For ecotoxicologists we engaged with SETAC for certification. Currently, 8 ecotoxicologists are certified and 4 others are following the procedure to become certified. In 2023, we will evaluate the added value of certification of our ecotoxicologists and do a proposal on how to continue.
2. 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. **Response Ctgb:** *Based on the Plant Protection Products and Biocides Act and embedded in European regulations and guidances, the Ctgb is responsible for both risk assessment and risk management in the authorization of plant protection products and biocides. The Board decides on individual applications on the basis of rules drawn up by the legislator.* *The Plant Protection Regulation only exceptionally provides a basis for a risk management decision that deviates from the outcome of the assessment. In many cases, this involves imposing restrictive measures to keep the risk of application within acceptable limits. The exception to this is the decision on an emergency measure (exemption). The authority for this decision has therefore been left to the minister,*	
who decides on the basis of (public) advice from NVWA (agricultural necessity) and Ctgb (risks and risk mitigation measures). *The Biocidal Products Regulation provides more grounds for taking social needs into account. In these cases, the assessment of whether there is a public need for the authorization of a product is carried out by RIVM. In these well-defined cases, the Board therefore makes a distinction between assessment and management decision and the grounds for that decision are transparent to the interested party. The RIVM report is available to the applicant and, if desired, third parties.* *The Board accepts the IVC's recommendation to formulate the distinction between risk assessment and risk management as clearly as possible and to do justice to both aspects as transparently as possible.*	
2a. 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. **Response Ctgb on recommendations IVC2018:** *The Ctgb will organize the internal processes with regard to decision-making in such a way that the distinction between risk assessment and risk management becomes more clearly visible in the discussions in the Board, in the representation of the decision-making process and in the representation of the decision. This will be implemented in an amended format of the cover note and of (the explanatory notes to) the decision. The head of the Scientific Assessment and Advice department will attend the Board meetings to ensure input from the risk assessment.*	**Update March 2023** The process for a more clear distinction between risk assessment and risk management (plant protection) was agreed upon by the Board (see here) and implemented in 2020. For biocides a procedure will be implemented when more experience with decision making for BPR dossiers is obtained.
2b. 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. **Response Ctgb on recommendations IVC2018:** *In line with the foregoing, the distinction between risk assessment and risk management as it takes shape in the discussions will also be reflected in the reports.*	**Update March 2023** See 2a: in relevant cases, minutes explicitly distinguish risk assessment and risk management arguments. See for example risk management decision to exclude use of glyphosate products in the Meuse catchment area or as pre harvest treatment (page 8, so called 'other considerations').
2c. 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. **Response Ctgb on recommendations IVC2018:** *It is standing policy to store all correspondence regarding an application in the DMS document management system. Where necessary, this will be enforced more strictly and improvements will be made.*	**Update March 2023** Following a European tender process in 2019, the Ctgb started the multi-year 'OBSO' program to renew the outdated IT application landscape (including Document Management System). With the new IT applications and the Record Management Application setup, the correspondence of the various parties is archived correctly. This extensive program will continue in 2023. 'OBSO' stands for an organisation-wide collaboration platform. An audit on archiving of relevant documentation (in DMS) related to product applications has been carried out. As a result of this audit, process improvements have been implemented for archiving documentation.
3. 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. **Response Ctgb:** *The Ctgb notes with great pleasure that the IVC considers that the work of the Ctgb is of high scientific quality. The IVC's view that the Board's role in the "peer review" process can be seen as a "best practice" is also recognized and experienced as such.*	
3a. 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. **Response Ctgb on recommendations IVC2018:** *Where the decision making from the peer review process in the EU deviates from the interpretation of guidances by the Ctgb, this information is fed back to the Board in writing. The feedback from the European process will be given a more prominent place in the cover note. Principle issues are listed separately. Based on this, the Board will discuss what this means for decision-making and for (future) Ctgb policy.*	**Update March 2023** An internal policy for sharing feedback from the EU process (both for PPP and biocides) with the Board was agreed upon in 2020. This policy includes internal feedback and learning from EU comments for future dossiers, sharing relevant info with the

	Board and a process on Board involvement in active substance dossiers during the EU phase. In addition, a separate working procedure on Board and Secretariat responsibilities during the BPR referral phase (either getting a referral or initiating a referral) was established.
3b. 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. **Response Ctgb on recommendations IVC2018:** *The Ctgb plays an active role in Europe to improve cooperation between all parties. It is good to read that the IVC expresses its appreciation for this. Participation in OECD seminars and expert groups in the Netherlands is divided among the Ministry of LNV, RIVM and Ctgb. The Ctgb actively participates in the expert group on biopesticides. A discussion in the OECD expert group on biopesticides (June 2018) showed that EU Member States are reluctant to participate in joint evaluations of active substances based on their previous experience with this process. The Ctgb is open to participation in such joint reviews if this contributes to knowledge exchange in the assessment of new classes of substances, especially when such a substance forms a sustainable alternative for agriculture.*	**Update March 2023** No additional action required.
3c. 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. **Response Ctgb on recommendations IVC2018:**	**Update March 2023**

All scientific assessors of human toxicology follow an ERT training. Part of this training is training in non-dietary human exposure risk assessment. For scientific assessors Human Toxicology (for PPP) and scientific assessors for Residues, there are clear agreements at European level in the field of exposure (OPEX, PRiMO), employees are trained "on the job", and through participation in conferences and workshops. *For scientific assessors Human Toxicology (for Biocides), uniform practices regarding exposure are still under development. Depending on the approval of the active substance, agreements are made per PT (product-application combination) in Ad hoc working groups, such as ARTFood. RIVM takes the lead in this (methodology development), but in close coordination with the Ctgb. For this group of scientific assessors, it will be determined whether there are additional specialized training courses for exposure assessment and whether these are of added value.*	All human toxicologists are ERT certified (or in the process to become certified) and trained on the job during dossier assessment and courses or conferences. This includes dietary as well as non-dietary exposure. For PPP, harmonised guidance documents for dietary (PRIMO) and non-dietary (OPEX) exposure assessment are available. For biocides, this is not always the case. On a case by case basis for specific uses in certain product types assessment methodologies are developed and agreed on in ad hoc working groups. For the development of assessment methodologies, the RIVM is in the lead in the Netherlands. Ctgb experts are indirectly involved via RIVM. Furthermore, for difficult or controversial issues we are in close contact with RIVM experts (e.g. neurotoxicity, cumulative effects, disinfection byproducts etc). It was concluded they we do not need additional training at this stage, but we keep track of new developments for which we may need separate training.
3d. 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. **Response Ctgb on recommendations IVC2018:** *The Ctgb uses external experts to carry out some of its tasks, either because the knowledge is not available in-house or in order to cope with peaks in capacity demand. With regard to sharing knowledge, so that the Ctgb does not need to have all knowledge areas in-house, agreements have been made with the RIVM and the NVWA. The Ctgb also works together with WUR (Wageningen University & Research). The policy of the Ctgb is that, in principle, the permanent staff must be able to do the work, for the sake of quality and quality control. However, the hiring of external capacity is occasionally necessary in order to cope with a peak in the planning or an*	**Update March 2023** The use of external scientific expertise remains necessary to be able to absorb peaks in capacity demand. In the period from 2019 to 2022, an average of around 3% (of the realized billable hours) per year in hours was allocated to external experts. (2019; 3600 hours - 2020; 3600 hours - 2021; 2668 hours and 2022; 3800 hours)

unforeseen shortage of capacity. The hiring of external capacity on an annual basis is a maximum of 3%. *With regard to outsourcing, the Ctgb has an internal control program to guarantee the scientific quality of the output, confidentiality and the exclusion of potential conflicts. This check program consists of the following components:* • The Ctgb works together with selected external parties (contract laboratories, consultants), who work under a Service Level Agreement (SLA) and confidentiality agreement. The SLAs are regularly evaluated. The selected external parties are listed on the Ctgb website (https://www.ctgb.nl/over-ctgb/organisatie/voorkomen-belangenvertangleling). • In addition, internal peer review always applies to a product from an external consultant, which guarantees independence and objectivity. *The IVC's recommendation and the principles for outsourcing will be included in the strategic planning 2020-2025, where a reassessment can take place if necessary.*	

Overview of the developments outside and within Ctgb since 2018

Overview of the developments outside and within Ctgb since 2018

Overview of developments outside and within Ctgb since 2018 (Ctgb July 2023)

Our stakeholders, the society, politics, and the Ctgb, everything continuously keeps changing and developing. In the timeline below we have made an overview of the highlights of the last years. The different items have more or less impact on our work and we hope this overview will support the IVC2023 in the meetings and interviews with the Board, management team and Ctgb staff.

2019	• publication EU Green Deal (11 December) • publication national Vision for the Future of Plant Protection 2030 • Ctgb has relative 'green' portfolio of applications, due to experience combined in our 'green team' • publication of the RIVM research on plant protection products and exposure of residents (in Dutch: OBO onderzoek) • European Commission decides that 4 Member States will perform the renewal assessment of glyphosate (FR, SE, HU, NL) • from 2019 and onwards: financial situation of the Ctgb is improving each year • new EU policy on endocrine disruptors is into force: additional work also for ongoing applications • new Ctgb secretary / executive director (1 July: Luuk van Duijn retires, succeeded by Ingrid Becks) • Ctgb reduces the number of applications we accept for biocides • IT project OBSO (development of an organization-wide collaboration platform) started in May • risk management decision by the Board (Dec. 2019) for the limited assessment of biocides (in Dutch abbreviated as GBO) under the Dutch transitional law (C-332.I.07)
2020	• covid: change from working in the office (with many colleagues working at home 1 day/week, as maximum) to 100% working at home • during the year we could make use of WebEx for videoconferences; till that time everything by phone and e-mail • a lot of additional work on hand disinfection products (emergency authorisations) • publication EU Farm-to-Fork strategy • publication EU chemicals strategy for sustainability • Brexit; UK had e.g. many applications as rapporteur member state and important contribution to development of guidance documents. Brexit increased European wide capacity problem. • at Ctgb disbalance in capacity between the teams (capacity issues for human toxicology; PPP and biocides) • Ctgb contribution to development of EU bee guidance • increasing public and political concern possible relation between exposure to PPP and neurodegenerative diseases • increasing public and political concern cumulative effects of PPP • huge request for disclosure of information, takes years to do this • implementation of the limited assessment of biocides under the Dutch transitional law (GBO; 1 September)
2021	• covid: large part of the year working at home • relatively high number of staff leaving the organization • scarcity in labour market • huge workload at Ctgb: focus on main tasks. Requests for work (in the broad sense, applications, guidances, contribution to training programmes, etc.) in addition to the annual work plan will in principle be rejected • a lot of additional work on hand disinfection products (regular authorisations) • at Ctgb disbalance in capacity between the teams (capacity issues for human toxicology; PPP and biocides) • start national transparency program coordinated by the Dutch government. Goal is to improve the archiving of data and e-mails, to support faster disclosure of information in the future. Ctgb also participates. • Ctgb switches to another organization for the ISO certification, CIIO
2022	• covid: large part of the year working at home. During the year changing to new hybrid situation, working partly in the office and partly at home • scarcity in labour market • start war in Ukraine (MRL's) • draft Sustainable Use *Regulation* (currently: Sustainable Use *Directive*) • new Ctgb chair of the Board (1 July: Johan de Leeuw retires, succeeded by Rob van Lint) • huge workload at Ctgb: focus on main tasks. More critical consideration on 'need to know' and 'nice to know'. E.g. decided to reduce number of 'theme sessions' for the Board. • at Ctgb disbalance in capacity between the teams (capacity issues for human toxicology; PPP and biocides). Disbalance is reducing. • we also reduce the number of applications we accept for plant protection • Once every 5 years Ctgb is evaluated (based on national law; Ctgb is an independent governmental organization. In Dutch ZBO), commissioned by the ministry of agriculture, with regard to effectiveness and efficiency. This has been done by AEF, a consultant, for the period 2016-2020. • start process to develop Ctgb strategy for 2024-2027 • Ctgb management team decides on 'further development of the organisation' • new Dutch transparency law 'open government' into force (Woo; 1 May) • agenda and minutes Board meetings published on Ctgb website, starting in January • backlog legal cases (legal objections and appeal) reduced to almost zero

2023	• impact of covid and the new balance between working in the office and at home on the commitment of our staff to the organization and to each other?
	• scarcity in labour market
	• Board adopts Ctgb strategy for 2024-2027. Strategic focus points:
	  - We commit ourselves to reduction of the lead times of applications
	  - We facilitate the sustainability of the active substance and products package
	  - We contribute to a better insight in the long term health effects of plant protection products and biocides
	• 2 October: implementation 'further development of the organisation'
	• implementation OBSO

List of information requested by IVC2023

List of information requested by IVC2023

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

7. To facilitate the work of the IVC2023, 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 IVC2023 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

8. 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:

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

a. A document detailing the response of the Ctgb management and Board to the 11 individual recommendations made by the IVC2018 in their report and a summary of the progress made since 2018 in these specific areas.
b. Inventory of and access to all technical, procedural and guidance documents relating to the scientific process that are currently in use – those introduced since 2018 to be identified.
c. Inventory of and access to legal documents relevant for the work of the Ctgb – those introduced or amended since 2018 to be identified.
d. 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 2018 to be identified.
e. Detailed organisational chart of scientific staff and management – changes since 2018 to be highlighted.
f. CVs, descriptions of functions and responsibilities, including identification of critical functions of all staff and Board Members.
g. Access to Declarations of Interest (DOI) of all scientific staff over the last 4 years.
h. Access to reports/documentation on internal and external scientific peer review processes and evaluations.
i. Access to documentation on procedures for dealing with formal complaints by dossier owner(s) and interested third parties and records of how these complaints have been addressed, including the history (4 years) of formal appeals.
j. Access to written communications with applicants.
k. Access to documentation on Mutual Agreement (MR) procedures.
l. A list of plant protection DARs, Biocide CARs and product authorizations granted since January 2018, together with details of the identity (ISO Common names) and content of the active substances they contain and in the case of product authorisations:-
    a. the formulation types (GIFAP Code);
    b. an indication to identify those for which the Ctgb conducted a zonal evaluation
    c. an indication to identify those for which another Member State conducted the zonal evaluation relied upon,
    d. 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
m. 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 IVC2023 were considered.
n. Access to operations manuals and SOPs prepared for use by scientific staff and dossier managers (co-ordinators) – those introduced since 2018 to be identified (to the extent not included in item a).
o. Access to policy and operational guidance prepared for Board members in making management Decisions on proposals submitted – those introduced since 2018 to be identified.

The list of requested items will be submitted to the Ctgb secretariat by the end of 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 IVC2023 during the course of its work.

Caveat with respect to requested documentation

10. It should be clear that, whereas the 3rd IVC considers the above-mentioned requests relevant for carrying out is evaluation, it is aware that many of the available documents addressing some, or all, the requests listed above may not available in English and that time and budget do not allow for the translation of a substantial number of documents into English. Consequently, the 3rd IVC is willing to focus primarily on documents (in English) that the Ctgb management and Board would consider of importance for the work of the ICV in the present context. Any suggestions in this respect would be highly appreciated.

Interviews

11. 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 24th and 25th 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. The Committee also wishes to speak with the Board members. Provisionally 22nd March is earmarked for these interviews (see also under Time Schedule).

Requests for Information and Documents Relevant to the Visitation (IVC2023)

The following list of items, documents and other materials are considered necessary for the evaluation to be undertaken by the IVC and the information is requested as soon as possible. In particular a) response to previous recommendations, b) the organisation staff chart and c) the list of plant protect products and biocides processed since 2018 should be given priority please. Further documentation and information may be requested where necessary by the IVC2023 during the course of its work.

a. A document detailing the response of the Ctgb management and Board to the 11 individual recommendations made by the IVC2018 in their report and a summary of the progress made since 2018 in these specific areas.

b. Detailed organisational chart of scientific staff and management – changes since 2018 to be highlighted. We will also wish to have access to

   i. CVs, descriptions of functions and responsibilities, including identification of critical functions of all staff and Board Members.
   ii. 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 2018 to be identified.
   iii. Declarations of Interest (DOI) of all scientific staff over the last 4 years.

c. A list of plant protection DARs and DRARs prepared by Ctgb, Biocide CARs and product authorizations granted since January 2018, together with details of the identity (ISO Common names) and content of the active substances they contain and in the case of product authorisations:-
   i. the formulation types (GIFAP Code);
   ii. an indication to identify those for which the Ctgb conducted a zonal evaluation
   iii. an indication to identify those for which another Member State conducted the zonal evaluation relied upon,
   iv. an indication to identify those authorised following the mutual recognition of an authorisation granted by another Member State.

   Examination of the list of compounds/formulations considered since 2018 will enable the IVC to select dossiers of plant protection products and biocides for detailed evaluation of the scientific process and their trail through Ctgb. In these cases the following additional information is requested:

   <u>Information associated with the scientific process for compounds selected</u>
   v. 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
   vi. Access to written communications with applicants.

   <u>Generic documentation used in the scientific process</u>
   vii. Inventory of and access to all technical, procedural and guidance documents relating to the scientific process that are currently in use – those introduced since 2018 to be identified. Access to reports/documentation on internal and external scientific peer review processes and evaluations.

27th February 2023

   viii. Access to documentation on procedures for dealing with formal complaints by dossier owner(s) and interested third parties and records of how these complaints have been addressed, including the history (4 years) of formal appeals.
   ix. Access to operations manuals and SOPs prepared for use by scientific staff and dossier managers (co-ordinators) – those introduced since 2018 to be identified
   x. Access to documentation on Mutual Agreement (MR) procedures.

   <u>Decision making</u>
   xi. Access to policy and operational guidance prepared for Board members in making management Decisions on proposals submitted – those introduced since 2018 to be identified
   xii. 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 IVC2023 were considered.

d. Access to protocol/guidelines on procedures of internal and external communication

e. Inventory of and access to legal documents relevant for the work of the Ctgb – those introduced or amended since 2018 to be identified.

<u>Caveat with respect to requested documentation</u>

It should be clear that, whereas the 3rd IVC considers the above-mentioned requests relevant for carrying out is evaluation, it is aware that many of the available documents addressing some, or all, the requests listed above may not available in English and that time and budget do not allow for the translation of a substantial number of documents into English. Consequently, the 3rd IVC is willing to focus primarily on documents (in English) that the Ctgb management and Board would consider of importance for the work of the ICV in the present context. Any suggestions in this respect would be highly appreciated.

14th April 2023

Request for specific dossier access

Block 1: "Conventional" chemical pesticides, European and National authorisation processes

Selection criteria: Ctgb acting as RMS, chemical pesticides excluding basic substances and those expected to be of relative low risk and Ctgb PPP authorisations. As the coverage is five years, the full process (a.s. EU assessment; EU approval decision; MS PPP assessment; and PPP authorisation) cannot be covered within the assessment period. From the provided list and database information, the selection covers the assessment as RMS including public consultation and parallel assessments of PPPs.

AS: **chemical a** NL as RMS

PPPs: **2 products**

Block 2: Implementation of regulatory obligations on risk mitigations

Selection criteria: Ctgb not acting as RMS but commenting during the EFSA peer-review. New legal approval decision including request to MS to consider risk mitigation measures for specific aspects considered of priority relevance for the Netherlands.

AS: **chemical b**

PPP:**1 product**.. New authorisation

Priority elements:

— the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment;

— possible presence of residues in rotational crops;

— the possible transfer of residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;

— the protection of groundwater under vulnerable conditions.

AS: **chemical c**

PPP:**1 product**. Change of authorisation and Procedural extension authorisation period

Priority elements:

— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;

— the protection of non-target plants.

14th April 2023

Block 3: Exception approvals, issues of scientific and societal concern, and comparison of PPP and BP processes

Selection criteria: Non-approved pesticide AS with exceptional authorisations granted by Ctgb, also authorised as biocides, and with identified concerns for bees/pollinators.

AS: **chemical d**

PPP: **2 products.**

BP: To be decided, for some products the Ctgb database includes an "Evaluation report" in English, but not for all. As first step, the request is for the evaluation reports or equivalent to all products with new authorisations or changes in the authorisation supported by a new Ctgb (re)assessment during the last 5 years.

Block 4: Contributions to the peer-review process of microbial pesticides

microbial pesticide e (NL co-raporteur) (2022)

NL contribution to peer-review of **microbial pesticide f** (2022)

NL contribution to peer-review of **microbial pesticide g** (2022)

NL contribution to peer-review of **microbial pesticide h** (2022)

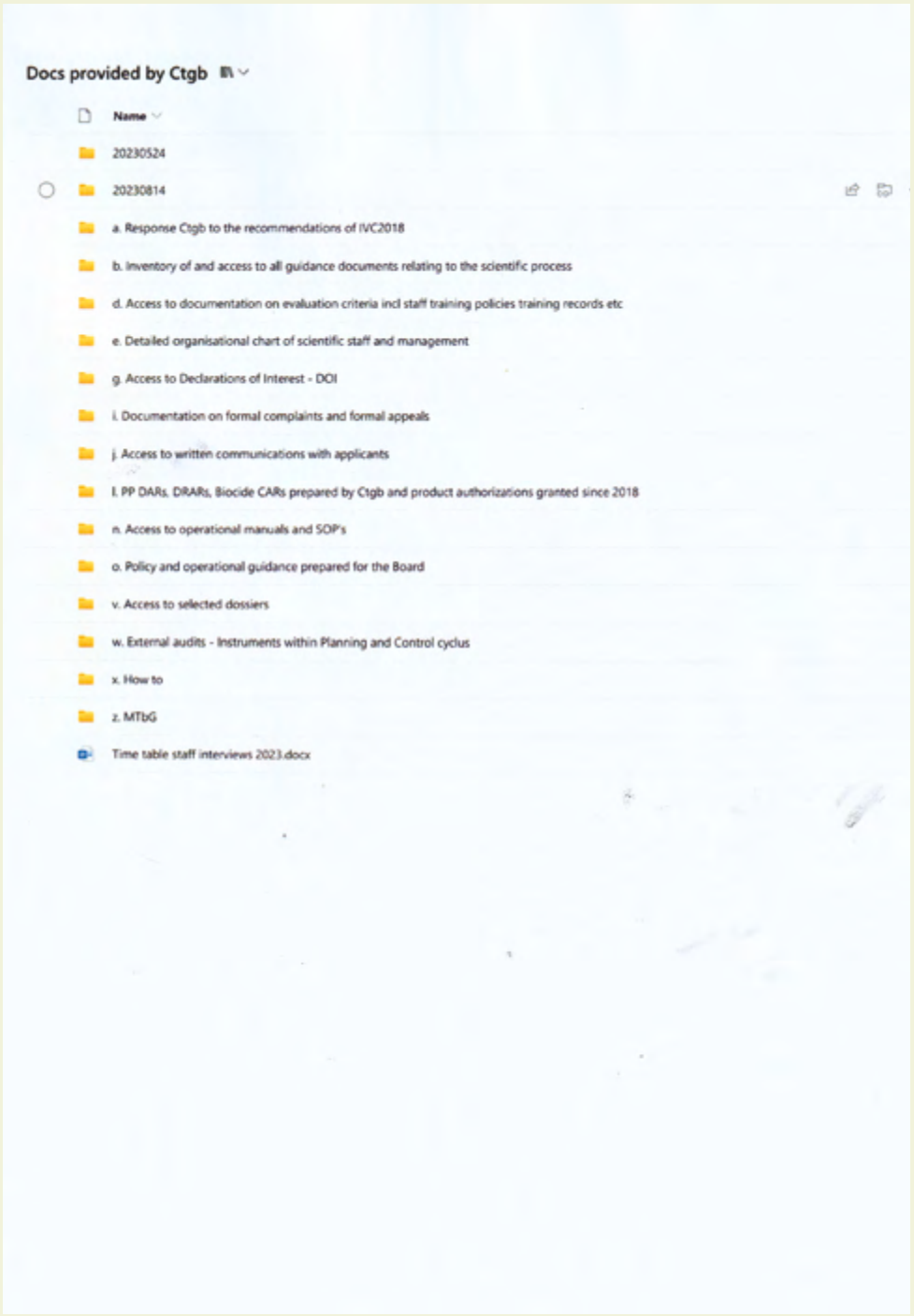
Block 5: potentially harmful and unacceptable effects, comparative assessment and substitution, Integrated Pest Management and sustainable use, One Substance One Assessment

1. List of cases and examples of the communication, where the NL / Ctgb has informed the Commission and other Member States about potentially harmful and unacceptable effects of PPPs and biocides based on Art. 56 of 1107/2009 or Art. 48 of 528/2012 in last 5 years. How is this information reflected in the Board decisions and in the communication with applicants and stakeholders?

2. List of cases of comparative assessments of PPPs containing candidates of substitution based on Article 50 of 1107/2009 in last 5 years. Examples of how the comparative assessments did / did not change the authorization decisions of PPPs. How is this information reflected in the communication with applicants and stakeholders?

3. Evidence of the scientific support of the Ctgb to the Dutch Ministry for the negotiations in the Council about the Commission proposal on the sustainable use regulation, for instance about the Integrated Pest Management issues. What is the impact of the Ctgb in preparing the views of the NL for the Council?

4. Evidence of involvement of the Ctgb staff in the preparation of the One Substance One Assessment approach in the risk assessment, and how the scientific staff are trained for this new procedure?


Docs provided by Ctgb
Name
20230524
20230814
a. Response Ctgb to the recommendations of IVC2018
b. Inventory of and access to all guidance documents relating to the scientific process
d. Access to documentation on evaluation criteria incl staff training policies training records etc
e. Detailed organisational chart of scientific staff and management
g. Access to Declarations of Interest - DOI
i. Documentation on formal complaints and formal appeals
j. Access to written communications with applicants
l. PP DARs, DRARs, Biocide CARs prepared by Ctgb and product authorizations granted since 2018
n. Access to operational manuals and SOP's
o. Policy and operational guidance prepared for the Board
v. Access to selected dossiers
w. External audits - Instruments within Planning and Control cyclus
x. How to
z. MTbG
Time table staff interviews 2023.docx

List of staff interviewed on site 24th-26th May 2023

List of staff interviewed on site 24th-26th May 2023

Time table staff interviews

Day:24 May 2023			
	Team	**Interviews with**	**Interviewers**
9:00 – 10:00	Eikenzaal Meeting to inform IVC on Reorganisation and Development new 5 year strategy	Ingrid BECKS-VERMEER, Nicole van STRATEN	Tony Hardy Sari Autio Alberto Mantovani Elizabeta Mičović
10:00 - 11:00	Eikenzaal Meeting of the IVC with the Board	Rob van LINT Herman EIJSACKERS Annemarie van WEZEL	Tony Hardy Sari Autio Alberto Mantovani Elizabeta Mičović
break			
11:15 – 12:15	Beukenzaal Stakeholder survey, Servicedesk, Communication policy	Hans van BOVEN (former team leader Communication) Geert Jan MOLEMA (Account manager PPP - communication with applicants) Gerda van den BOSCH (Servicedesk to inform applicants and general public)	Elizabeta Mičović Tony Hardy Sari Autio Alberto Mantovani
	Room B		
Lunch break			
13:00 - 14:00	Beukenzaal Policy advice	Rob van DRENT, Jan Willem ANDRIESSEN	Tony Hardy Sari Autio Alberto Mantovani Elizabeta Mičović
	Room B		
14:00 - 15:00	Beukenzaal Jurists	Ingrid BROEKE (leader of the Jurists team) Manon KONINGS (jurist)	Elizabeta Mičović Albert Mantovani Tony Hardy Sari Autio
	Room B		
break			
15:15 - 16:00	Internal consultation IVC		
16:00 - 17:00	Beukenzaal Assessors Green team	Anne STEENBERGH; Marieke van HULTEN; Olivier LANGEVOORT	Sari Autio Alberto Mantovani Elizabeta Mičović
	Room B		
Day:25 May 2023			
	Team	**Interviews with**	**Interviewers**
9:00 - 10:00	Beukenzaal Assessors Fate, Ecotox (PPP and Biocides)	Merel van de PLOEG, Elvira de LANGE, Greta WEIMA Maarten KLUNDER	Jose Tarazona Tony Hardy Sari Autio Alberto Mantovani Elizabeta Mičović
	Room B		
10:00 - 11:00	Beukenzaal Project planning applications	Diaz KROEZE Margreet Eerd-van PUTTEN Sarah de KRUIJFF Brigitte NOORLOOS	Sari Autio Elizabeta Mičović Tony Hardy Alberto Mantovani José Tarazona
	Room B		
break			
11:15 – 12:15	Esdoornzaal Management	Nicole van Straten Manager Scientific assessment and Advice	Tony Hardy Sari Autio, Alberto Mantovani Elizabeta Mičović José Tarazona
	Room B		
Lunch break			
13:00 - 14:00	Beukenzaal Business Operations	Ivonne VAN GEERENSTEIN (Manager Business Operations) Nicole VERLANGEN (Teamleader Personnel & Organisation) Lennart SANTBERGEN (Senior advisor Business operations)	Tony Hardy Sari Autio, Alberto Mantovani Elizabeta Mičović José Tarazona
	Room B		
14:00 - 15:00	Beukenzaal Assessors Human Toxicology & Residues (PPP and Biocides)	Angelique WELTEN, Chantal POLMAN, Andre SIMONS, Lisa ROBBERS	Tony Hardy Sari Autio, Alberto Mantovani Elizabeta Mičović José Tarazona
16:00 - 17:00	Eikenzaal Wrap up and first observations. Tony Hardy	Ctgb Senior Management team, Chairman of the Board	
Day:26 May 2023			
	Team	**Interviews with**	**Interviewers**
9:00 - 10:00	Beukenzaal Assessors Environmental Fate (PPP) Assessors Toxicology (Biocides)	Anton POOT Marcia BODERO	José Tarazona
	Room B		

Scrutinised dossiers evaluated by IVC

Scrutinised dossiers evaluated by IVC

Annex 11

Comments on assessment reports of selected Product Dossiers scrutinized by the IVC 2023

A. Biocidal active substance (Candidate for substitution) with product types PT 2 and PT 3 and
B. Biocidal active substance (Candidate for Substitution) with product types PT 2 and PT4
C. PPP active substances (Candidate for Substitution), azole resistance, NL ZRMS

Criteria and comments

1. Compliance with legislation and guidance documents

The national and zonal assessment reports and mutual recognition decisions produced by the Ctgb seem to be in compliance with the relevant and adopted EU guidances and the biocides and PPP legislation.

2. Clarity and comprehensibility of the Scientific Opinion

Clarity and comprehensibility of the Assessment Reports attached to the Board Decisions are high and the conclusions reached are clear.

3. Weight of evidence considerations

In general, the conclusions are clearly based on the data and the supporting documentation provided. The possible alternatives were presented but a full assessment of alternatives was not always available due to different assessment schedules of different active substances and product types.

4. Evidence of collegiate feedback and/or peer reviews

To some extent it was difficult to follow because of the Dutch language, but where exchanges and comments are in English they show clear and well-argued reasoning. The applicants were consulted appropriately during the assessment and preparation of the Board decision.

5. Level of consistency and coherence

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

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

Where relevant, the principal documents have been accepted by the international players.

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

Where appropriate, the documented comments appear to have been considered.

8. Other criteria

A summary of the conclusions of the Board was available also in English, which was an improvement since the last evaluation by the IVC in 2018.

9. Overall statement

The overall impression was that the different roles of the Ctgb as zonal ZRMS, commenting CMS and mutual recognition MRS were conducted effectively, clearly and with scientific balance and, in general, good documentation. In many cases, it was not possible to substitute the uses with less hazardous alternatives.

D. Cases of information about unexpected hazardous effects (Article 56 Reg 1107/2009 and Article 47 Reg 528/2012)

Criteria and comments

1. Compliance with legislation and guidance documents

The national assessment reports and decisions produced by the Ctgb seem to be in compliance with the relevant and adopted EU guidances and the biocides and PPP legislation.

2. Clarity and comprehensibility of the Scientific Opinion

Clarity and comprehensibility of the Assessment Reports attached to the Board Decisions are high and the conclusions reached are clear.

3. Weight of evidence considerations

In general, the conclusions are clearly based on the data and the supporting documentation provided. A substitution with less hazardous products was not possible in all cases, but use instructions were amended in the national authorizations aiming to better avoid the hazardous effects.

4. Evidence of collegiate feedback and/or peer reviews

To some extent it was difficult to follow because of the Dutch language, but where exchanges and comments are in English, they show clear and well-argued reasoning. The applicants were consulted appropriately during the assessment and preparation of the Board decision.

5. Level of consistency and coherence

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

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

Where relevant, the principal documents have been accepted by the international players. The information provided by the NL has been discussed regularly within the EU fora.

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

Where appropriate, the documented comments appear to have been considered. The information provided by the NL has been appreciated by the other Member States and discussed regularly within the EU fora.

8. Other criteria

A summary of the conclusions of the Board was available also in English, which was an improvement since the last evaluation by the IVC in 2018.

9. Overall statement

The overall impression is that the Ctgb actively gathers information about effects of active substances and distributes it to other Member States in a timely manner. The NL seeks harmonized procedures between the EU Member States in this matter.

Elements selected for the detailed ad hoc assessment

The IVC2023 evaluation process of the scientific assessment framework included a complementary process for ad hoc assessment.

The first point was a detailed evaluation of the scientific elements of the assessment frameworks for pesticides and biocides, covering the manuals, the European, zonal and national working arrangements guidances and documents, the information the Ctgb intranet, and the science related elements of the Shared drives of the different Science Teams.

The focus was for the evaluation of the manuals was on consistency, clarity and transparency, assessing the capacity of the manuals and supporting documents for providing a clear and transparent framework to applicants, and to facilitate the Ctgb staff assessments, in order to achieve a high level of coherence, consistency and scientific excellence.

Some of the elements verified in the manuals and complementary material are described below.

- The manuals are maintained updated
- The different sections of the manual present and detail sufficiently the differences between the different assessment frameworks (EU a.s., national product assessment, PPP zonal assessment, BP transitional assessment, ...)
- The national and zonal requirements and deviations from EU assessments are clearly presented and properly justified
- Inconsistencies, flaws, and pending issues lacking consensus are clearly presented and the NL view is provided when relevant
- References to supporting information, such as EFSA TR on recurring issues, are provided
- Issues no covered by EU guidances and requiring implementation at national level are included
- Special provisions and agreements, such as acceptance of draft OECD guidelines, are included
- There are detailed indications regarding specific tools and manuals developed for the national assessments

The verification confirmed the overall excellent quality of the manuals and additional documents, some recommendations for further improvement has been proposed. Then, the *ad hoc* assessment moved to the next step, verifying that the a.s. and product assessments conducted during the period under evaluation have been conducted in line with the manuals and relevant assessment frameworks. This process included the verification of the relevant specific elements in the internal documentation provided by the Ctgb and in publicly available documents from the Ctgb and EU agencies web sites.

The dossiers selected for this assessment included

- Three dossiers on the assessments of chemical pesticide a.s. and PPP with Ctgb acting as RMS,
  - One dossier on the renewal of an existing substance,
    - Complemented with the assessment of consistency in three dossiers on national authorisation of PPP containing this active substance
  - One dossier on amendments of approval conditions, and
  - One dossier on assessments of a new active substance
- Four dossiers on EU assessments of biocidal a.s. commented by Ctgb covering the following categories PT 1,2,3,4,5, 6, 14 and 19
- Three dossiers addressing the Ctgb comments during the commenting rounds of EU assessments of pesticide chemical a.s., covering
- Three assessments of PPP for zonal and national assessments with Ctgb as zonal RMS and with Ctgb commenting other assessments
- Selected documents from national assessments of PPP and PB products containing the a.s. selected above and more than one a.s.

Conclusion

The documents confirmed the overall high scientific excellence of the Ctgb assessments, that the relevant assessment framework had been followed, and no major issues or inconsistencies were detected. A main element for consideration by the Ctgb as highlighted in the report, is the prevalence of regulatory *versus* scientific consistency, exemplified by the use, in the national assessments of products, endpoints agreed in the previous assessment but not further supported by the ongoing Ctgb renewal assessment.

Procedures for evaluating the legal case studies

Annex 12

Procedure for evaluating the legal case studies

The Ctgb provided the IVC 2023 with a summary of objections and complaints for the evaluation, as presented before in Chapter Legal support. Having access to the Document Management System of the Ctgb, the IVC 2023 could search independently for information of the legal cases on an ad hoc basis. Additionally, during the interviews with the legal team, questions were made to gather an overview on what kind of legal issues the Ctgb is typically facing now. Also during the interviews with the Board, legal issues were discussed. All the information that the IVC requested, was kindly provided by the Ctgb.

Colofon

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Sanne Fonteijn-Roseboom
'Graanveld'
Digital Landscape Artwork

Graphic Design:
Waar Ontwerp, Arnhem
Gertie Beurskens

Information

Ctgb

office address
Bennekomseweg 41
6717 LL Ede
The Netherlands

ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden