

Ctgb Annual Report 2015

Foreword

During the year under review the Ctgb made a strong commitment to further harmonisation, equal implementation of European legislation and equal assessment of dossiers in the various European countries. Having the same rules in all Member States of the European Union for plant protection products and biocides should make national variations in implementation an exception. The Ctgb wants to help ensure that the assessments in the various countries take place in the same way. Good contact between the competent authorities helps to promote a level playing field in Europe.

As a result of this aspiration, the Ctgb has examined its own policy guidelines about mutual recognition and minor uses and has updated them in accordance with the European model. The Ctgb continually participates in discussions with colleagues in other Member States and takes the lead on various themes. For example, the Ctgb chairs the Biocides Coordination Group, in which the Member States attempt to solve disagreements by means of coordination and consultation. Previously, solving such disagreements required mediation and a decision from the European Commission. Furthermore, in the Ctgb has also taken the responsibility for more than half of the applications for Union authorisations; this is a new option for authorising biocidal products for the entire European market all at once. As part of the Union authorisation, a single Member State performs the assessment, the other Member States discuss the results, and the European Commission makes the final decision. In cooperation with the European Chemicals Agency (ECHA), the Ctgb is helping to make the Union authorisations feasible in practice.

During the year under review, 'green' products received a great deal of attention, which is crucial for the future of plant protection. Based on the demand in society for more 'green products', the industry is developing more environmentally friendly plant protection products. These are products of biological origin, based on bacteria, fungi and viruses, which can control or eliminate pests and diseases. For example, you can use natural enemies of plant diseases and pests to protect a crop. Generally speaking, the risks of these green products for humans, animals and the environment are usually lower than the risks for chemical products. The disadvantage is that the efficacy is not always 100%. To achieve greater efficacy, green products must often be used in combination. The Ctgb wants to facilitate the 'greening' of plant protection products in the authorisation and assessment system. In 2014, the Ctgb therefore signed the 'Green Deal for green plant protection products'. In 2015, two green products were authorised, and the Ctgb is currently assessing two substances and two additional products.

The Ctgb also aims to promote 'green thinking' in Europe. In November we held a workshop about the assessment of the toxicology of biological substances to reach agreement on these aspects for the European Union. This workshop was attended by representatives of 14 Member States, the European Food Safety Authority (EFSA) and the European Commission. It established the basis for new working agreements, which will be specified in a European committee.

The annual Ctgb client contact day also had a 'green' character. The Minister for Agriculture, Sharon Dijksma, gave the keynote speech and officially opened the new offices of the Ctgb. In her speech, she called on the attendees to work together to make the product assortment more sustainable and to strive for a level playing field: equivalent assessments and procedures throughout Europe.

During the year under review, many discussions focused emphatically on the distinction between hazard and exposure, especially concerning neonicotinoids and bee mortality, and on imidacloprid contamination of surface water near greenhouses. After studying a report from the EASAC (European Academies Science Advisory Council), the Ctgb concluded that the report contained no new data. As a result it decided not to review the assessments of neonicotinoids. However, the Ctgb did suspend the authorisation of the related product Potatoprid, because research in Denmark had shown that bees also forage on flowering potato plants. Using this product on potatoes therefore leads to excessive risk for bees.

In the vernacular, hazard and risk are often used as synonyms. For the assessment of plant protection products and biocides, however, there is a world of difference between these concepts. The societal debate often concerns the hazards – the toxicity – of a plant protection product or biocide. But many household products that can be purchased at the supermarket are also toxic. It depends on how they are used. This determines the risks for humans, animals and the environment. Without exposure, there is no risk. As part of the assessment, the Ctgb therefore not only looks at the hazards of a substance, but also conducts an extensive review of the actual exposure during and after use. We calculate the risk based on various scenarios, which we then used to determine whether, and/or under which conditions, the product can be used safely.

To prevent contamination of surface water near greenhouses with imidacloprid, the Ctgb – based on research conducted by Alterra – previously recommended the modification of existing guidance documents. The use of the product was restricted even further in 2014 with a wastewater treatment requirement. In 2015, a study conducted by CML (the Center for Environment Sciences of Leiden University) showed that the quality of the surface water had not improved, despite these measures. Because the new requirements had only recently been in force at the time of the measurement, the Ctgb will perform measurements again in March 2016 to determine whether mandatory wastewater purification indeed has a beneficial effect. If the quality of the surface water has still not improved, then the Board will intervene by limiting the use of the corresponding products or withdrawing their authorisations.

The Board is pleased that 2015 closed with a positive operating result.

In addition, Prof. dr. Tinka Murk stepped down from the Board at the end of 2015 due to commitments from her new position as Professor of Marine Biology. The Board is very grateful for her professionalism and engagement.

Finally, I would like to express my thanks and appreciation to all our staff, who with great dedication and involvement, have made the further development of our organisation possible.

Ir. Johan F. de Leeuw
Chair

2015 in a nutshell

The most important task of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is to assess applications for authorisation of plant protection products and biocides and to make decisions about such authorisations. This must be done competently and diligently so that society can have confidence in the fact that the products, if used correctly, are safe for humans, animals and the environment. The Ctgb performs this task in a complex environment involving agriculture, nature, the environment, national and European governments and industry. The Board is aware of this position and accounts for its decisions in publications and through its transparent operation and methods.

During the year under review, the emphasis was on European harmonisation, greening and innovation, and on the discussion about risk and exposure. For our own organisation, an important event was moving to our new offices in Ede.

Harmonisation

During the year under review, the movement towards harmonisation, equal implementation of European legislation and equal assessment of dossiers in the various European countries continued unabated. The European Union is essentially a common market in which the authorisation of plant protection products and biocides has been harmonised and in which manufacturers of these products can operate under the same conditions. In practice however, there are still national variations. The Ctgb wants to actively contribute to further harmonisation of the assessment process. Improved contacts between the competent authorities in various Member States improve the quality of the work and reduce the differences between them. This promotes a level European playing field.

At the request of the Minister for Agriculture, the Ctgb examined the current state of harmonisation in Europe. The Ctgb determined that a harmonised assortment of products is feasible only in the long-term. This is because the renewal cycle for products is 10 to 15 years, resulting in the continuation of old authorisations for a relatively long period. Now that the European Regulation for plant protection products has been in force for a number of years, the Ctgb has critically examined its own policy guidelines on mutual recognition and minor uses. This involved comparisons with the objectives of the Regulation with its application in practice by other Member States. On this basis, the Ctgb basis recalibrated and updated its policy guidelines. The Ctgb conducted an intensive dialogue with colleagues at authoritative institutes in other Member States, and took the lead in resolving disagreements on specific dossiers.

The Biocidal Products Regulation provides a number of practical instruments to promote harmonisation. One of these is the Biocides Coordination Group, which has the task of resolving disagreements between Member States about a specific dossier through coordination and consultation as a first step. A formal disagreement procedure can be initiated only after this step is completed. The Coordination Group thus fulfils an important role in the harmonisation between Member States. The Ctgb has offered to chair the Group. The Coordination Group frequently solves disagreements between countries by means of consultation, whereas mediation and a decision of the European Commission (EC) were previously required.

In 2015, the Ctgb was responsible for the assessment of more than half of the applications for a Union authorisation, a new procedure which enables biocidal products to be authorised at once for the entire European Union. This also reflects the leading position taken by the Ctgb in this area. As part of a Union authorisation, a single Member State performs the assessment, after which the other Member States discuss the results, and the European Commission makes the final decision. In cooperation with the European Chemicals Agency (ECHA), the Ctgb works out the details of the Union authorisations to make them feasible in practice.

Greening

The future of plant protection lies in a more integrated approach, which is referred to as 'greening'. Due in part to the societal demand for more 'green products', the industry began to innovate in a more environmentally friendly

direction. This is also compatible with the scientific and technological developments that make it possible to understand the complex systems in crop production and to approach them in a more integrated fashion. This means approaching them with a coordinated set of interventions such as improved seeds, cutting and bulbs, soil improvements, natural enemies and plant protection products that improve the health of crops. The Ctgb looks for routes in the current authorisation system to make this innovation possible. In June 2014, the Ctgb therefore signed the 'Green Deal for green plant protection products'. The aim of the Green Deal is to accelerate the implementation of more sustainable plant protection in agriculture and horticulture, and to eliminate unnecessary obstacles for applicants seeking authorisation for such green products. The project has a term of two years. A pilot project is currently ongoing to acquire experience with the assessment of green products.

Green products – or 'biologicals' – do not have a chemical origin, but a biological one. For example they are based on microorganisms such as bacteria, fungi or viruses. The risks of these products for humans, animals and the environment are usually, but not always, lower than the risks of chemical products. However, the efficacy it is often lower as well. Green products prevent, inhibit or displace a pest or disease and lead to less chance of resistance because more alternatives are available. Last year, the dossiers for two green substances and four green products were received for assessment, of which two products have now been authorised. In dialogue with the applicants, the Ctgb has also learned a great deal in the pre-application process about the risks and omissions in the dossier with such green products, and where possible has sought pragmatic solutions. As part of the Green Deal, the Ctgb is building a Biologicals team for the assessment of such substances and products, and is coordinating the assessment of biological products.

In November, the Ctgb held a workshop on the assessment of the toxicology of substances based on microorganisms with the aim of making agreements for all of Europe. This workshop was attended by representatives of 14 Member States, the European Food Safety Authority (EFSA) and the European Commission. The workshop established the basis for new working agreements and for the committee that will give shape to the European guidance documents that will specify these agreements.

To attain a more sustainable product assortment, on 1 June 2016 the principle of comparative assessment will go into force. This comparative assessment is intended to reduce the toxicity load on humans, animals and the environment. If the active substance in a plant protection product is on the European list for substitution, then it must be determined at the national level whether suitable alternative products or methods are available. In the Netherlands, the Ctgb takes this role. If alternatives with lower risks for humans, animals and the environment are available, then the specific use will no longer be authorised for the substance concerned. In this way, plant protection products containing candidates for substitution are gradually being replaced by methods and products with a lower risk. However, the alternatives must be at least as effective as the product in question. Growers must be able to continue to rotate products in order to prevent resistance from developing in the future.

What does such an assessment involve? A substance becomes a candidate for substitution based on a number of risk aspects, such as persistence in the environment. If another product scores a factor of 10 lower on one of these risk aspects, this product can be used to replace the candidate for substitution. Subsequently, the Netherlands Food and Consumer Product Safety Authority conducts an agronomic comparison. It determines whether effective alternatives are available. If this is the case, then the Ctgb conducts a risk assessment.

During the annual client contact day (11 June 2015), Minister for Agriculture Sharon Dijksma formally opened the new offices of the Ctgb (see the text box 'A transparent and open new building'). In her speech, she called on attendees to work together on a more sustainable product assortment and to work towards a level playing field: equivalent assessments and procedures throughout Europe.

Hazard and exposure

The Ctgb authorises products under strict conditions in order to limit the exposure of humans, animals and the environment to the active substance. Within these conditions, the risks are contained and the product can be used safely. This balance between exposure and risk remains difficult to explain. Without exposure, there is no risk.

Nevertheless, the outside world often sees only the risks, and it is difficult for people to understand that the risks of these 'toxic products' do not apply if they are used correctly.

During the year under review, for example, the neonicotinoid family of plant protection products was a topic of discussion and concern. The EASAC (European Academies of Science Advisory Council) called for the European Commission to review the status of these products because they believed that the authorisation system had not sufficiently considered the hazardous effects. Neonicotinoids not only kill pests that are harmful to the crop, but also kill pollinating insects, such as honeybees and bumblebees, as well as other organisms. As a result, the natural ecosystems in agriculture could be weakened over the long term. The report, actually a summary of the existing literature, only discussed the hazards of the substances, while the actual exposure when the products are used correctly in the Dutch and European context was not taken into account. Moreover, the EASAC did not consider the conditions for use and the authorisation requirements to which the substances were subjected. As a result, many of the risks described in the report cannot occur because they are prevented by the legal conditions for use. Based on this report, the Ministry of Economic Affairs (EZ) requested the Ctgb to review the authorisations. The Ctgb ascertained that the EASAC report did not present any new data. Most of the considerations referred to above had already been taken into account during the authorisation process and a supplementary reassessment. The products concerned are safe to use as long as the growers comply with the legal conditions for use and restrictions. The EASAC report therefore did not justify intervention in the existing authorisations.

In November, however, the Ctgb decided to suspend the authorisation of the related product Potatoprid because new research from Denmark had shown that the potato is an attractive crop for bees. Bees also forage – to a limited extent – on flowering potato plants. The use of the product therefore entails excessive risks for bees.

To prevent contamination of surface water with imidacloprid in the vicinity of greenhouses, the Ctgb – based on research conducted by Alterra – previously recommended modifications of existing guidance documents. This was done to protect mayflies, which are an important food source for birds and other animals. Moreover, the use of imidacloprid had already been restricted in 2014 and 2015; as a result growers without wastewater purification systems could no longer buy this product. Despite these measures, a study conducted by CML (the Center for Environment Sciences of Leiden University) showed that the quality of the surface water had not improved. Because the new conditions for use had not been in force for very long, the Ctgb is conducting another series of measurements beginning in March 2016 to determine whether the mandatory wastewater purification indeed has a beneficial effect on surface water quality. If it appears that these measures have not been sufficiently effective in reducing the concentration of imidacloprid in surface water, the Board will recommend limiting its use or take measures regarding the authorisation itself. (see text box 'Mandatory wastewater purification with use of neonicotinoids in greenhouses').

At the recommendation of the Health Council of the Netherlands and at the request of the Minister for Agriculture and the State Secretaries of the Ministry of Infrastructure and the Environment (IenM) and the Ministry of Health, Welfare and Sport (VWS), the Ctgb conducted a study into the risks for local residents of the use of existing plant protection products. The study began with an investigation of the uses in flower bulbs and fruit growing. Among other methods, the study used a new model from EFSA to calculate the specific effects for local residents. Until now, these effects were included as part of the assessments for the users. The study showed that none of the products entail a major risk for local residents. The models that the Ctgb used for this purpose have also been shown to be adequate for more stringent assessment requirements

Turnaround time of applications

In 2015, in general decline could be seen in the turnaround time. Three zonal applications (with the Netherlands as rapporteur) were completed within the statutory period. Regarding applications for which the Netherlands is Concerned Member State (CMS), more and more assessments have also been completed within the statutory period of 120 days. However, this declining trend flattened out at the end of 2015. This was caused by temporary understaffing. We always try to coordinate supply and demand as closely as possible, but it is also difficult for applicants to accurately predict the number of dossiers they will submit and when they will submit them.

The turnaround times for completing biocidal product applications are acceptable. In 2015, all the applications that were planned in the operational budget were completed on time.

Organisation and finances

In 2015, the multiyear strategy of the Ctgb for 2016-2020 was drafted. The identity, mission and vision of the organisation were reviewed, further refined and developed, and then used to prepare a multiannual programme. To link the multiyear strategy with the expectations of stakeholders, last spring a roundtable discussion was held with important stakeholders based on a draft version of the programme. Their response was included in the final version. The multiyear program was then converted into a multiyear budget and the operational plan for 2016. Various parts of the plan were worked out in further detail, the main objectives were formulated and the activity clusters were defined.

During the year under review, much effort was invested in bringing the staff up to strength and keeping it there. This resulted in a net increase of 1 FTE. In 2015 more employees left Ctgb than in previous years; exit interviews were held with these employees to determine the reason for their departure. These reasons included increasing opportunities in the labour market. The results of the exit interviews were used to prevent undesired staff turnover. In 2015 we also recruited new employees, and at the end of the year conducted interviews with candidates who began working in 2015. The expansion of the workforce has focused on the primary departments, with positions as scientific assessors, project leaders and policy officers. To prevent the formation of excessive overhead, when filling vacancies for support personnel we always look critically at whether additional employees are truly needed.

In 2015 the organisation decree from 2014 was completed. In view of the large size of the initial Wba department, it was split into two new departments: the Scientific Assessment and Consultancy (Wba) department, which consists of the scientific assessors, and the Board Advisory & Project Planning department (C&P), which consists of project leaders and planning advisors. For these 'new' departments, the managers were also appointed. In March, the new deputy Secretary/Director (Dr. Ingrid Becks-Vermeer) was appointed with the approval of the Board. The other organisational developments during the past year can be found in the chapter Organisation & Personnel.

Financial results

The Ctgb closed 2015 with a positive operating result of €105,000. This was achieved despite the fact that the workforce scarcely increased and the absenteeism rate (5.7%) was high. The positive operating result was credited to the general reserve, resulting in another reduction in negative equity.

Communication with stakeholders

In 2015, the Ctgb began implementing its new strategic communication plan. The composition and formation of the Communication team was adapted accordingly. One result of the strategic communication plan was the renewed house style. The Ctgb works in the interest of humans, animals and the environment, and this trichotomy is reflected visually in the house style used for all Ctgb communication. At the beginning of June, the restyled website with the new house style also went online.

Ctgb client contact day

The Ctgb client contact day on 11 June 2015 was held simultaneously with the official opening of the new offices in Ede by Sharon Dijksma, the Minister for Agriculture at that time. More than 200 visitors attended this fourth Ctgb client contact day. In a relaxed atmosphere, they were informed about Article 43 (renewal of products), the Green Deal for green plant protection products, biocidal product families and Union authorisations. In the afternoon, breakout sessions were held on various aspects of the movement towards greening and sustainability.

Among societal stakeholders (politics, NGOs general public), there was a great deal of attention for the greening of plant protection products, neonicotinoids (imidacloprid), glyphosate and formaldehyde. The news coverage about these substances and the Ctgb was influenced primarily by several ongoing objection procedures against specific

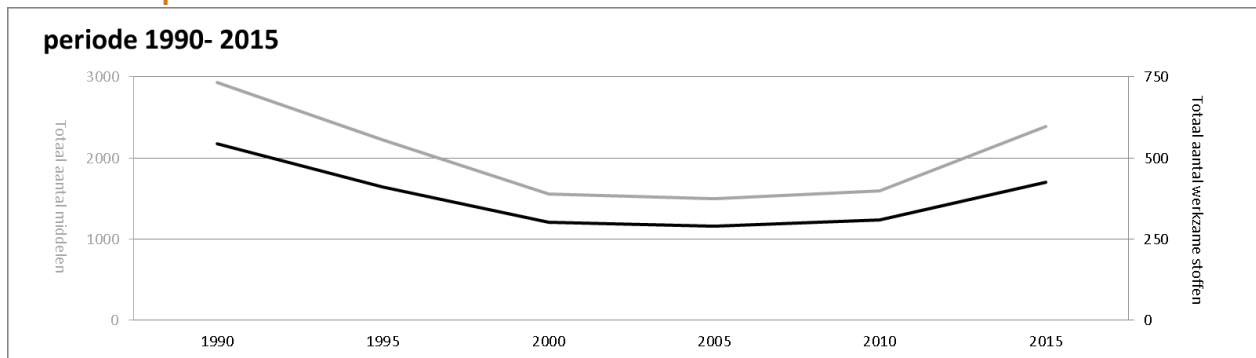
authorisations. By means of press releases and Internet publications, we clarified the position and role of the Ctgb in these cases. Due to this development, a decision was made to take a more proactive role in 2016 regarding the image component 'trust'.

Digital information

During the year under review, many visitors logged onto our website (108,508 unique visitors compared to 83,190 in 2014). More than 66.5% visited the site regularly, and more than 67% of the visitors consulted the authorisation database. The percentage of visitors from abroad rose to 75% compared to 70% in previous years.

Our Twitter account now has nearly 1000 followers. The account is very active regarding the above-mentioned substances and products. The Ctgb generally responds with a tweet linking to specific pages with an explanation about its role and duties with respect to such topics. In addition, the Ctgb used Twitter primarily as a means to spread news quickly.

Authorised products and active substances



Mandatory wastewater purification with use of neonicotinoids in greenhouses

During the year under review, the neonicotinoid family of plant protection products was a topic of discussion and concern. The EASAC (European Academies of Science Advisory Council) called for the European Commission to review the status of these products because they believed that the authorisation system had insufficiently considered the hazardous effects. Neonicotinoids not only kill pests that are harmful to the crop, but also kill pollinating insects such as honeybees and bumblebees, as well as other organisms. As a result, the natural ecosystems in agriculture could be weakened over the long term.

More stringent conditions

The Ctgb ascertained that the EASAC had not presented any new data. The considerations referred to above had already been included in the assessment during the authorisation process and a supplementary reassessment. The products concerned are safe to use as long as the growers take account of the legal conditions for use and restrictions. Therefore, the EASAC report did not justify intervening in the existing authorisations; however, the Ctgb did make recommendations to modify the existing guidance documents.

Risk and exposure

At issue in the discussion is the relationship between risk (toxicity) and exposure. If something is toxic, that does not mean that the product should be forbidden, because the Ctgb limits exposure by means of the legal conditions for use. As result, the product is safe for humans, animals and the environment. For example, the use of imidacloprid was restricted in 2014 and 2015; as a result, growers without wastewater purification systems can no longer buy this product. To prevent surface water contamination, the purification system must remove at least 99.5% of these substances from the wastewater.

Beneficial effect

The Ministry of Economic Affairs requested CML (the Center for Environment Sciences of Leiden University) to provide an overview of surface water quality. During the measurement period (until March 2015), they determined that the water quality had not yet improved. The Ctgb believes that this period was too short to determine whether the more restrictive legal conditions for use had a beneficial effect on surface water quality (wastewater purification for greenhouse cultivation became mandatory on 1 May 2014). If the new monitoring data indicate that water quality has still not improved, the Board will intervene by restricting use or withdrawing the authorisations for the corresponding products.

The new offices are transparent and open

Last summer, the Ctgb moved into its new offices on the Bennekomseweg (Horapark) in Ede, only a few minutes' walk from the Ede-Wageningen train station. It is a light and open building, situated between trees on the edge of the forest. Minister for Agriculture Sharon Dijksma performed the opening ceremony.

Ambience

"The ambience of our previous offices in Wageningen was no longer compatible with the organisation that we want to be", explains manager of operations Ivonne van Geerenstein. "We were hidden away in our former building and difficult to find. The building was dark and oppressive, and employees experienced it as oppressive. The facilities were obsolete, and we had leakage and other problems. In the meantime, the Ctgb had grown rapidly due to the enormous increase in applications. We no longer had room to grow."

"The Ctgb wants to be accessible, open and transparent", she continues, "with a peaceful ambience that implies connection, both internally and with the outside world. The scientific assessors, policy officers and support staff must be able to walk easily into each other's offices. The previous offices made cooperation difficult and were truly constricting."

Glass

The new offices invite cooperation: the walls are made of glass, creating a literally transparent ambience in the entire building. The natural colours and the green in the interior architecture connect with the nature outdoors. Several strikingly designed lamps and works of art provide allure, drawing attention from the essentially plain design. The existing furniture was reused in a smart way. On the two floors occupied by the Ctgb, possibilities for contact or asking a quick question are present everywhere. There are large rooms for receiving guests and holding workshops.

Moreover, the new offices, including renovation, are actually less costly than the old building in Wageningen, the Ctgb is more easily accessible, both by public transport and by car, and there is plenty of parking. As a result, visitors from other EU Member States can now attend workshops at walking distance from the train to Schiphol airport. "In fact, we see only advantages", says Van Geerenstein.

ISO 9001:2008 certificate

The Ctgb wants to be predictable and transparent about the quality that it provides, and in this way to show how it fulfils its statutory task. To provide legal equality and legal certainty, the structure of the activities is stipulated in processes that can be monitored and inspected. The Ctgb is periodically inspected by various bodies. For example, in 2013 an international committee (*Visitatie Commissie*) reviewed the decisions of the Board.

ISO standards

In 2015, the ISO 9001 certificate was renewed. ISO standards also provide a way to achieve transparency. The certification is based on the following: you say what you do, you do what you say and you demonstrate this, and all this takes place according to a system in which an organisation continuously improves the management system and adapts it to changing conditions.

Approval

Certiked, an accredited certification body, has reviewed the quality management system at the Ctgb and given another three-year 'approval'. Salient positive aspects in the Certiked assessment include the structured and simple way in which the Ctgb provides access to information, and the workshops that it organises. These aspects standardise and safeguard the expertise of the Board and the engagement with applicants and the public.