

Study of how some member states within
the EU work in order to reach the deadlines
in the evaluation process for plant protection
products

PM 5/16



The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

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Foreword

In December 2015, the Government commissioned the Swedish Chemicals Agency to follow up the handling of authorisations for pesticides and to propose solutions for an improved balance in the authorisation process for pesticides. The basis for these proposals is to secure a continued high level of protection for human and animal health and the environment¹.

As a part of the commission the Swedish Chemicals Agency should describe how other member states within the same zone (the northern zone) and larger member states within the EU work in order to meet the EU harmonised deadlines with maintained protection for the environment and health during evaluation of applications on permits to sell and use plant protection products. The Swedish Chemicals Agency commissioned Ramböll Management Consulting to conduct an interview-based study including eight countries within the EU. Project manager at the Swedish Chemicals Agency was Viktoria Axelsson.

This PM summarises the study on how the eight EU-member states work in order to meet the harmonised deadlines with maintained protection for the environment and health during evaluation of applications on permits to sell and use plant protection products.

The opinions and recommendations presented in the study are entirely those of the author and do

¹ Swedish Chemicals Agency Report 5/16, March 2016, “Uppföljning av handläggning av prövningsärenden”. The report is available on the Swedish Chemicals Agency website www.kemikalieinspektionen.se

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Summary

In December 2015, the Government commissioned the Swedish Chemicals Agency to follow up the handling of authorisations for pesticides and to propose solutions for an improved balance in the authorisation process for pesticides. The basis for these proposals is to secure a continued high level of protection for human and animal health and the environment².

As a part of the commission the Swedish Chemicals Agency should describe how other member states within the same zone (the northern zone) and larger member states within the EU work in order to meet the EU harmonised deadlines with maintained protection for the environment and health during evaluation of applications on permits to sell and use plant protection products. The Swedish Chemicals Agency commissioned Ramböll Management Consulting to conduct an interview-based study including eight countries within the EU.

The study shows that there are several common elements of success among the member states, such as the importance of explicit directives and prioritisation of activities, good quality of the applications, maintaining and developing in-house competence, effective internal processes as well as the authorities' ability to themselves decide upon the fees. These are also factors that agree with the ones decided in the action plan by the Swedish Chemicals Agency, as well as suggested in previous budget proposals.

The study does also show that that even though, in many cases, the challenges for the countries are similar, they have different conditions based on financing, scope, organisation, control of the activities etc., which affect the way in which the responsible authorities can meet the challenges. The authorities have also progressed to different degrees in their work to reach the EU harmonised deadlines.

² Swedish Chemicals Agency Report 5/16, March 2016, "Uppföljning av handläggning av prövningsärenden". The report is available on the Swedish Chemicals Agency website www.kemikalieinspektionen.se

Sammanfattning

Kemikalieinspektionen fick i december 2015 i uppdrag från regeringen att följa upp handläggningen av prövningsärenden och föreslå lösningar till förbättrad balans i handläggningen av ärenden om bekämpningsmedelsprodukter. Utgångspunkten för förslagen är ett fortsatt säkerställande av en hög skyddsnivå för människors och djurs hälsa och för miljön³.

Som en del i detta uppdrag ingick att Kemikalieinspektionen skulle beskriva hur andra medlemsländer inom samma zon (norra zonen) och större medlemsstater inom EU arbetar för att nå de EU-harmoniserade tidsfristerna med bibehållet skydd för miljö och hälsa vid prövning av ansökningar om tillstånd att få sälja och använda växtskyddsmedel. Kemikalieinspektionen gav Ramböll Management Consulting i uppdrag att genomföra en intervjubaserad studie med åtta länder inom EU.

Studien visar att det finns flera gemensamma framgångsfaktorer bland länderna, bland annat vikten av tydlig styrning och prioritering av verksamheten, bra kvalitet på ansökningarna, att kunna behålla och utveckla kompetensen, effektiva interna processer samt myndigheternas möjlighet att själva kunna disponera avgifterna.

Studien visar också att även om utmaningarna i många fall är liknande för länderna så har de olika förutsättningar utifrån bland annat finansiering, organisation och styrning av sina verksamheter, vilket i sin tur påverkar ansvariga myndigheters sätt att anta utmaningarna. Myndigheterna har också kommit olika långt i sitt arbete med att nå de lagstadgade tidsfristerna.

³ KemI rapport 5/16, mars 2016, "Uppföljning av handläggning av prövningsärenden". Rapporten är tillgänglig via Kemikalieinspektionens webbplats www.kemikalieinspektionen.se

1 Introduction

The Swedish Chemicals Agency has faced challenges in terms of meeting the EU harmonised deadlines for evaluation of applications on authorisation of plant protection products in accordance with Regulation (EC) No 1107/2009 and has been criticised by the Office of the Chancellor of Justice for the long processing times. In December 2015, the Government commissioned the Swedish Chemicals Agency to describe how other member states within the same zone (the northern zone) and larger member states within the EU work in order to meet the EU harmonised deadlines with maintained protection for the environment and health during evaluation of applications on permits to sell and use plant protection products⁴.

As part of this task, the Swedish Chemicals Agency commissioned Ramböll Management Consulting (hereinafter referred to as Ramböll) to conduct an interview-based study including eight countries within the EU. The countries included in the study were Denmark, Finland and Lithuania from the northern zone, as well as the larger EU countries France, the Netherlands, Poland, Great Britain and Germany.

In the study, Ramböll has, after analysing their data of interviews and document studies, presented information from the countries' work and experiences of the evaluation process of applications for plant protection products. A deeper, interview-based study was conducted of Denmark, the Netherlands and Great Britain as these countries have managed to meet the deadlines to a certain extent and they described that they worked actively to attain this. Several insights regarding the working processes in the different countries have been made through this study.

This PM summarises the study on how the eight EU-member states work in order to meet the harmonised deadlines with maintained protection for the environment and health during evaluation of applications on permits to sell and use plant protection products.

2 Results

2.1 Knowledge of the market and companies provides better conditions for authorities to predict the influx of applications in the long term

A common challenge for all countries is dimensioning of the activities and to have a good advance planning in the evaluation activities. A success factor for meeting deadlines is having good predictability on the influx of applications in the longer term. The countries participating in this study are active to varying degrees in terms of contact with the market and the companies. In the Netherlands, specific persons within the authority, referred to as "account managers" have been commissioned to proactively keep track of companies and the market where one aim is to create a better understanding of companies' planning routines. In this way, they may be aware of how the influx of applications to the authority will be structured. Also Denmark conducts annual meetings with national trade associations in order to grasp the market's conditions. Better market awareness contributes to better opportunities for authorities to plan their activities.

⁴ Swedish Chemicals Agency Report 5/16, March 2016, "Uppföljning av handläggning av prövningsärenden". The report is available on the Swedish Chemicals Agency website www.kemikalieinspektionen.se

2.2 Work actively with the companies to receive better applications

A particularly important factor which many emphasise for successfully restricting the time consumed in the evaluation process is that the applications are of a high quality – the better application, the less work for the authority and the better conditions for meeting the deadlines. Many countries therefore emphasise that one of the most prioritised measures is to work proactively with the applicant companies in order to ensure that the applications which are received are of as high quality as possible. The Netherlands and Great Britain have worked actively to adapt the proactive support to companies based on the needs of the companies in question. The pre-meetings are subject to a fee in the Netherlands and Great Britain. According to the Chemicals Regulation Directorate (CRD) in Great Britain, it is often beneficial to pay this fee as companies to a higher degree avoid later supplementations and a lengthy and more expensive processing. In France, the pre-meetings are free of cost and there the companies, together with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), are offered the opportunity to prepare a plan for the application and jointly plan the application submission date. By means of the pre-meetings, the ANSES also obtains a forecasting tool as the companies during the pre-meetings state when they expect to submit their applications.

Another measure for receiving better applications is that several countries have become more inclined to send back applications to the companies if the application is assessed as too poor and consequently will take a long time to process with several supplementation rounds. Several countries have clearly communicated that they have early screening of the application documents and that applications which are not up to the mark are sent back. This procedure is applied in Great Britain and the Netherlands, among others.

2.3 If the evaluation is divided among several organisations, very good planning and control are required to meet the deadlines

There is a connection between control over the evaluation process when external organisations are involved and the ability to meet the deadlines. External organisations may be an asset in terms of competence and resources and enabling implementation of the evaluation on time, despite a resource shortage in the own organisation. Evaluation processes in which external organisations participate, but where the responsible organisation does not steer or have control over the process, may delay the processing durations. Two examples of the latter exist in countries like Poland and Germany, and earlier France as well, where the evaluation process is conducted by several different organisations. In these countries it also appears to be difficult to re-direct resources from one organisation to another. In Germany it is particularly clear that if one of the four organisations which conducts evaluations experiences delays, then the entire process will be delayed.

Also the responsible authority in the Netherlands, the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), does often work with external organisations in the evaluation process, but under different conditions. The Ctgb appoints external evaluators on commercial grounds when they need to, such as when to expand their own resources or to receive assistance with specific competence. Appointing external organisations/companies in a consultative manner allows the Ctgb to itself stipulate deadlines and scale of the commissions. In France, there is also the opportunity to bring in external competence, but here it is a matter of obtaining expert opinion. In Great Britain, the CRD has the entire process within its organisation. Here, the CRD does not purchase external competence, but

ensures that more resources are involved if this is considered necessary. In order to plan its work, the CRD has a database for applications in which they monitor every application as well as a resource planning tool for their own staff.

2.4 By retaining fees the organisations can adapt their resources

In countries like France and Denmark, the trend in recent years has been that the authorities which conduct the evaluations also are able to command the fees that the companies must pay for the evaluation activities. In Great Britain and the Netherlands, the authorities also command the fees. Several of them describe that the opportunity to command the fees is an important prerequisite for being able to dimension and adapt the activities based on changes in the influx of applications by, for example, leasing or purchasing further resources. Denmark describes that the opportunity to command the fees results in the authority being able to plan and dimension the activities evenly in order to retain personnel. If the spontaneous influx of applications from companies is low, then the Danish agency indicates that it is willing to take the rapporteurship in the zonal cooperation.

2.5 The harmonised deadlines impose requirements on authorities to streamline the internal processes

The countries included in this study describe that streamlining the evaluation process internally in the organisations and optimising the flow is an ongoing process and is a prioritised development work. Identified areas include creating control of the time consumption of different subsections and determine the scope of different moments in advance – two things which require both planning tools and experience feedback in the system on how much time the different sections may take. Another prioritised area is the ability to conduct different parts of the evaluation in parallel. Other areas include introducing an electronic application system and streamlining documentation and archiving.

2.6 Control and prioritisation is important for handling evaluation within the deadlines

In most cases the assessment of the risks of the products for the environment and health is the most time-consuming part of the evaluation process. Given the tight deadlines, several countries describe that they have been forced to find ways to streamline this part of the evaluation. Among other things, it is stated that it is necessary to prioritise time on the risks which are the most important and to disregard the less important details which can cause delays in the evaluation. The balance between what constitutes more or less important risks is not an easy question, but requires competence and experience. The countries which work actively with control in the evaluation work, such as Denmark, describe that it is essential that both the departmental management group and experienced colleagues assume an active role in this process.

2.7 Adapt, retain and develop competence

The short deadlines and the need to steer towards the most important risks in the evaluation work require experienced personnel. Therefore it is important to retain and develop competence within the organisations. Both the Ctgb in the Netherlands and the Environmental Protection Agency (EPA) in Denmark emphasise the importance of offering stimulating and varying tasks in order to retain personnel and at the same time develop competence of the personnel. This takes place by involving the scientific officers in the method development and the work on the European cooperation, to name a few examples. In some countries the authorities do not have the opportunity to expand the workforce themselves, this primarily applies in countries where the evaluation is funded by grants. Countries such as Poland, Finland and Lithuania, describe that they do not have the opportunity to recruit new personnel despite facing problems with meeting the deadlines.

2.8 Discussions on values and roles have been necessary to encourage the staff to changes

Most countries are clear that current deadlines are a difficult challenge for the authorities. In some of the countries where they clearly have taken control of the activities to meet the deadlines, questions on how long the evaluations may take have been a prioritised matter within the organisation. The Netherlands and Denmark are open about that these questions have been the subject of a lot of discussions in each organisation, but that it was crucial to get the entire organisation to accept the changes which were considered necessary. The Netherlands describes that the organisation for one year spent time and efforts on discussions, which were open and impartial, in order to get the entire organisation to agree on the relatively significant changes that the tight deadlines entail.

2.9 Better coordination between countries within the zonal cooperation is necessary

The uncoordinated information sharing between countries is perceived as a problem in the evaluation process and is a challenge which largely lies outside the competence of the own country. Several of those interviewed demand a more coordinated process which is managed at an EU level. EPA in Denmark is able to meet the deadlines to a large extent and describes that several important steps have been taken in the northern zone to harmonise the evaluation process. Despite this, it is experienced that the agency's planning is impeded by delays of other member states. In France, it is difficult to meet the deadlines because of dependency on reports from other countries within their zone. The degree of harmonisation within the different zones seems to have progressed to different extents, and even though the northern zone has relatively good conditions there is potential for improvement.

3 Reflections from the eight countries in the study

All countries in this study have challenges in terms of meeting the deadlines for evaluating plant protection applications. The challenges are similar in all the countries, but they have different conditions and have progressed to different degrees in their work to develop a process to meet the processing durations.

3.1 Denmark

In Denmark, the evaluation of plant protection products is handled by the Danish EPA, an agency which falls under the Ministry of Environment and Food. The Danish EPA has the overall responsibility for the evaluation process, but the Danish Veterinary and Food Administration and Department of Agroecology conduct certain parts. The fees which applicants pay to the Danish EPA are commanded by the agency and should cover all costs for the evaluation. The Danish evaluation process is characterised by an open communication with applicants and a pragmatic approach towards any problems which arise during the evaluation.

Since January 2016, the Danish EPA does no longer have any backlog and now the agency processes 90 percent of new applications and renewed authorisations within the harmonised deadlines. The Danish EPA is also optimistic in terms of future opportunities of meeting deadlines. A fee system, which entails that the evaluation is now funded through fees which are commanded by the Danish EPA, was introduced in January 2014. Previously the evaluation was funded through grants from the national budget. According to the Danish EPA, the recently introduced fees have resulted in the agency obtaining higher resources, which is described as a success factor for meeting the deadlines. The Danish EPA also emphasises good monitoring of the market, good planning and clear directions as important success factors in terms of the agency's ability to meet deadlines. According to the Danish EPA, countries within the northern zone have taken several important steps forward in order to harmonise the product evaluation within the zone, but at the same time the Danish EPA claims that the agency finds it difficult to plan its own activities as other member states do not meet the deadlines.

3.2 Finland

In Finland, the Finnish Safety and Chemicals Agency (Tukes) is responsible for evaluation of plant protection products. The evaluation process is handled completely by Tukes and over recent years the agency has found it difficult to meet deadlines for evaluation of products, with the exception of mutual recognitions. Tukes has had a backlog for a few years. In May 2015, 40 percent of the applications received in 2012 and related to product authorisation had not been completed yet. The corresponding figure for 2013 was 90 percent. However, Tukes has managed to eliminate its backlog of applications according to Directive 91/414/EEC. According to Tukes, the delay in the processing is the result of that product assessments from the zone rapporteur Member State are late, and an internal resource shortage for conducting evaluations when Finland is the zone rapporteur Member State, to name some examples. Tukes now prioritises evaluations of active substances as a result of the resource shortage. Better application documents and more harmonised cooperation within the EU would contribute to more efficient processing according to Tukes.

A number of applications have been rejected over recent years as a result of a risk to the environment and health. According to Tukes, there are quite few plant protection products at the Finnish market. Due to this, it is in practice difficult to use comparability in the assessment and the evaluation of application. However, there are plans for negotiations with the Natural Resources Institute Finland on how to use their competence in the evaluation process for comparative assessments in the future.

3.3 France

The allocation of responsibility for the evaluation process for plant protection products in France has changed during 2015. The French Ministry of Agriculture and Food of the Forest has passed on the decision-making to the ANSES which was previously only responsible for the risk assessments. The ANSES has thereby been assigned greater responsibility and has also, during 2015, reorganised and developed the processes to be able to take the overall responsibility. In this work, it has been important to keep the handling of applications and the decision process separated from the risk assessment activities in order to guarantee the independence of the latter activities. During 2016, the ANSES is also preparing to take over the entire evaluation process of the biocidal products.

In the past, France has had major challenges in terms of meeting deadlines and it is now hoped that the new allocation of responsibility will improve the situation. In order to streamline the evaluation further, the ANSES works proactively with companies in order to improve the quality of applications, by early pre-meetings, and to get better predictability on the influx of applications by planning jointly with the companies about when the application is to be submitted. Internally, the ANSES is working on introducing an electronic application process, to develop the internal information system and to simplify the archiving activities. A significant part of the problem with deadlines relates to the cooperation with other EU countries, where late reports, or reports that are not published, impede and delay the work.

3.4 Lithuania

In Lithuania, the evaluation of plant protection products takes place within the State Plant Service under the Ministry of Agriculture. The department within the State Plant Service, which conducts all areas of the evaluation process, consists of 14 persons. Decisions on authorisation of plant protection products are primarily made by the Director of the State Plant Service. There is also a certain political dimension in the evaluation process as a statutory consultative committee consisting of persons from the ministry, state institutes and academia are responsible for providing proposals on decisions to the Director of the State Plant Service.

The State Plant Service meets the deadlines when Lithuania is a zone rapporteur Member State but is not as successful as concerned member state. The State Plant Service states that they only assume the role as zone rapporteur Member State for a limited number of applications and that these are particularly prioritised. According to the State Plant Service, long processing durations for applications where Lithuania is the concerned member state are explained by insufficient personnel resources. As the authority will probably not receive higher resources, the State Plant Service assesses that it will be difficult to meet deadlines in the future as well. In order to handle the authority's challenges, the State Plant Service works to improve the internal coordination by creating a better overview of how the work distribution and workload are structured over the department. The State Plant Service also offers free of cost pre-meetings with companies which will contribute to improved applications.

3.5 The Netherlands

In the Netherlands, evaluation of applications for plant protection products is conducted by the Ctgb. The Ctgb has the overall responsibility, but may appoint external organisations for, for example, efficiency assessments. The evaluation of plant protection products is funded

completely by fees which the authority commands. The fees cover both the Ctgb's internal costs and any costs of external evaluators. The fee levels are adjusted annually by the Ctgb.

The Ctgb states that they have problems with meeting deadlines. According to the European Crop Protection Association (ECPA), the problems can possibly be explained by employee turnover and accurate application of the regulatory framework. According to the Ctgb, success factors for meeting deadlines are applications with a high quality as well as good time management for the evaluation activities. In order to improve the quality of applications, different types of pre-meetings with applicants are offered. Before the evaluation process starts, a first check of the quality of the application is also conducted in which the Ctgb assesses the time consumption for the application. Over recent years, the Ctgb has worked to change the approach of employees to the evaluation process and persuade them to focus more on meeting the deadlines. In order to get a better overview of ongoing applications and facilitate that different areas are conducted in parallel and in a coordinated manner, the Ctgb has also commenced the work on developing a new planning tool.

3.6 Poland

In Poland, the Ministry of Agriculture and Rural Development of Poland as well as Department of Plant Breeding and Protection are primarily responsible for evaluation of applications for plant protection products. In addition to the Ministry of Agriculture and Rural Development, there are ten different organisations which can conduct the entire or parts of the evaluation process itself. Given that the responsible unit at the Ministry of Agriculture and Rural Development only has approximately 20 employees, the evaluation process can be described as decentralised and that the Ministry of Agriculture and Rural Development primarily assumes a project leader function. According to ECPA there are major delays in Poland.

According to the Ministry of Agriculture and Rural Development, they manage to absorb lessons from their own process and through exchange with other countries. There is confidence that the backlog and waiting durations can be reduced. In addition to this, the unit which works with plant protection products will increase its workforce by over 30 percent during 2016.

3.7 Great Britain

In Great Britain, the Health and Safety Executive and the CRD have the overall responsibility for evaluation of applications for plant protection products. The entire evaluation is conducted by the CRD. Interesting examples of the evaluation process include that companies are provided the opportunity to conduct two evaluations of applications per year with "fast track" and that companies have the opportunity to conduct preparatory meetings (subject to a fee). Another interesting procedure is that the CRD works with early sorting meetings in the process where each application is categorised in one of five different categories.

The CRD distinguishes itself by excelling in terms of meeting prescribed deadlines. According to them, there are several reasons for this. One is that the entire evaluation lies within the same organisation, and as a result, work processes can be synchronised and lessons can be integrated in the activities. Another explanatory reason is that the authority commands sufficient resources, as the CRD commands the entire fees. However, the CRD is not entitled to decide the fee levels alone and therefore they only cover costs of work, while the overhead costs are covered by grants.

The third reason is that they generally have a high quality of the applications which are received. The CRD has worked actively to get applicant companies to improve the quality of applications.

3.8 Germany

In Germany, the Federal Office of Consumer Protection and Food Safety (BVL) is the authority responsible for the evaluation process. The evaluation process includes three more different authorities and (according to ECPA) the process is complicated and difficult to steer. BVL is not able to meet prescribed deadlines. The German evaluation of applications is currently undergoing a review process.

4 Lessons and success factors from the evaluation processes in the countries

4.1 Challenges and success factors linked to meeting the deadlines and to ensure the protection for the environment and health

Several challenges and success factors for an efficient evaluation process have been identified within the framework of this study. An overview of these is shown in the table below.

Table 1. Identified challenges and success factors

	Challenges	Success factors
1	Dimensioning of the activities and to have good advance planning.	Good predictability on the influx of applications in the longer term and the ability of dimension the activities.
2	The evaluation process has become increasingly tighter and the responsible authorities have received increasingly clearer incentives to reduce the processing durations.	Establish a close contact with the companies in order to ensure that the applications which are received are of as high quality as possible as well as to develop the processes.
3	Countries with several organisations involved in the evaluation process have difficulty with combining different efforts.	Regardless of the number of organisations involved, it is important to have a resource planning tool.
4	Dimensioning of the resources depending on influx of applications.	That the authorities can adapt their resources based on working pressure - one way is by retaining the fees, another is by using external resources.
5	The harmonised deadlines place new demands on the authorities.	Planning tools, conduct different parts in parallel, electronic application system and streamlining documentation and archiving.
6	The assessment of the risks of the products for the environment and health is often the most time-consuming part of the evaluation process.	Control and management is important as the balance between what constitutes more or less important risks is not an easy question.
7	To retain experienced competence in the organisation.	To offer stimulating and varying tasks as well as competence development.
8	The deadlines mean new working methods which may seem strange for those who will implement them.	Communicate and anchor the necessity of the changes.
9	Information sharing and the dependency between countries.	There are no clear-cut examples but several authorities ask for a more coordinated process which is handled at an EU-level.

The overall challenge for all organisations, which are responsible for product authorisation of plant protection products, is to meet the prescribed deadlines. A reason for the imbalance in the handling of applications in relation to the deadlines is that the prescribed rules are perceived as too strict and that the organisations do not have adequate resources to handle the number of applications within the framework of the deadlines. A further challenge is the zone system in which countries are dependent on data from each other in order to be able to make decisions within the deadlines in the countries. Here, some countries claim that it often may be difficult to obtain requested information from other countries included in the same zone.

At the national level, there are authorities which have been able to meet deadlines in a better manner than others by, for example, proactive work with companies in order to obtain clear forecasts of the influx of applications as well as complete applications as possible. Great importance is also attached to the development and streamlining of one's own activities.

Even though, in many cases, the challenges for the countries are similar, they have different conditions based on financing, scope, organisation, control of the activities etc., which affect the way in which the responsible authorities can meet the challenges. All success factors have been highlighted by the countries, but it is also clear that some of the identified success factors to a certain extent may be problematic to unite. An example which may be perceived as contradictory is the conditions to adapt the resources based on incoming applications and at the same time retain and develop personnel. It seems that viewing the evaluation process from a holistic perspective is important for successfully meeting the deadlines and ensuring protection for health and the environment.

Below, the lessons which emerged most clearly in the study are described and exemplified.

4.2 Knowledge of the market and companies provides better conditions for the authorities to predict the influx of applications in the long term

A common challenge for all countries is dimensioning of the activities and to have good advance planning in the evaluation activities. A success factor for meeting deadlines is having good predictability on the influx of applications in the longer term. The countries participating in this study are active to varying degrees in terms of contact with the market and the companies.

In the Netherlands, specific persons within the authority, referred to as “account managers”, have been commissioned to proactively keep track of companies and the market where one aim is to create a better understanding of companies' planning routines. In this way, they may be aware of how the influx of applications to the authority will be structured. Also Denmark conducts annual meetings with national trade associations in order to grasp the market's conditions. Better market awareness contributes to better opportunities for authorities to plan their activities.

4.3 Work actively with the companies to receive better applications

The harmonised deadlines in the evaluation process have become increasingly tighter and the responsible authorities have received increasingly clearer incentives to reduce the processing durations. Many describe it as a major conversion work where they have had to re-think on how they work with and relate to the companies.

A particularly important factor which many emphasise for successfully restricting the time consumed in the evaluation process is that the applications are of a high quality – the better application, the less work for the authority and the better conditions for meeting the deadlines. Many countries therefore emphasise that one of the most prioritised measures is to work proactively with the applicant companies in order to ensure that the applications which are received are of as high quality as possible.

Within the framework of this study there are different examples where authorities provide information on the evaluation, offer consulting as well as different forms of pre-meetings in order to, in this manner, prevent companies from having to provide supplementation at a later stage.

The Netherlands and Great Britain have worked actively to adapt the proactive support to companies based on the needs of the companies in question. They offer different types of pre-meetings with varying aims, depending on the company's needs, where the company together with the licensing authority can review the application. The pre-meetings are subject to a fee in the Netherlands and Great Britain. According to the CRD in Great Britain, it is often beneficial to pay this fee as companies to a higher degree avoid later supplementations and a lengthy and more expensive processing. In France, the pre-meetings are free of cost and there the companies, together with the ANSES, are offered the opportunity to prepare a plan for the application and jointly plan the application submission date. By means of the pre-meetings, the ANSES also obtains a forecasting tool as the companies during the pre-meetings state when they expect to submit their applications.

Another measure for receiving better applications is that several countries have become more inclined to send back applications to the companies if the application is assessed as too poor and consequently will take a long time to process with several supplementation rounds. With the tighter harmonised deadlines, the authorities have received clear incentives to reduce processing durations and for many this represents conversion work. Several countries have clearly communicated that they have early screening of the application documents and that applications which are not up to the mark are sent back. This procedure is applied in Great Britain and the Netherlands, among others. France states that they now are indicating to companies that they intend to become tougher in the initial assessment. In the past, France has traditionally been known to ask many supplementary questions which in itself resulted in companies lacking incentives to submit an application as good as possible. Instead, they have waited for the supplementary questions from the agency. In many countries, the hunt for receiving perfect applications has now started.

4.4 If the evaluation is divided among several organisations, very good planning and control are required to meet the deadlines

Based on this study, it is clear that there is a connection between control over the evaluation process when external organisations are involved and the ability to meet the deadlines. External organisations may be an asset in terms of competence and resources and enabling implementation of the evaluation on time, despite a resource shortage in the own organisation. Evaluation processes in which external organisations participate, but where the responsible organisation does not steer or have control over the process, may delay the processing durations.

Two examples of the latter exist in countries like Poland and Germany, and earlier France as well, where the evaluation process is conducted by several different organisations. In these countries it also appears to be difficult to re-direct resources from one organisation to another.

In Germany it is particularly clear that if one of the four organisations which conducts evaluations experiences delays, then the entire process will be delayed.

Also the responsible authority in the Netherlands, the Ctgb, does often work with external organisations in the evaluation process, but under different conditions. The Ctgb appoints external evaluators on commercial grounds when they need to, such as to when expand their own resources or to receive assistance with specific competence. Appointing external organisations/companies in a consultative manner allows the Ctgb to itself stipulate deadlines and scale of the commissions. A condition for this is that the Ctgb commands the fees which companies pay for their application. To a large extent, the Ctgb works as a private company where it charges for all the services it performs. By means of the network of external consultants they can thereby adapt their resources completely depending on how many paying assignments they have at every given time.

In France, there is also the opportunity to bring in external competence, but here it is a matter of obtaining expert opinion. In Great Britain, the CRD has the entire process within its organisation. Here, the CRD does not purchase external competence but ensures that more resources are involved if this is considered necessary. In order to plan its work, the CRD has a database for applications in which they monitor every application as well as a resource planning tool for their own staff.

4.5 By retaining fees the organisations can adapt their resources

In countries like France and Denmark, the trend in recent years has been that the authorities which conduct the evaluations also are able to command the fees that the companies must pay for the evaluation activities. In Great Britain and the Netherlands, the authorities also command the fees. Several of them describe that the opportunity to command the fees is an important prerequisite for being able to dimension and adapt the activities based on changes in the influx of applications by, for example, leasing or purchasing further resources.

Denmark describes that the opportunity to command the fees results in the authority being able to plan and dimension the activities evenly in order to retain personnel. If the spontaneous influx of applications from companies is low, then the Danish EPA indicates that it is willing to take rapporteurship in the zonal cooperation.

A challenge in Great Britain is that the fees are assessed as too low. The fees were set five years ago and since then have not followed the inflation rate or the trend of workload. The CRD states that the fees need to be updated more often so that the CRD can cover its costs in a better manner. Now the fees cover most of the costs of work, while the overhead costs are covered by grants.

4.6 The harmonised deadlines impose requirements on authorities to streamline the internal processes

The countries included in this study describe that streamlining the evaluation process internally in the organisations and optimising the flow of applications is an ongoing process and is a prioritised development work. Already before the latest regulations in the Plant Protection Regulation (EC) No 1107/2009 were introduced, work was conducted to streamline the processes. The new harmonised deadlines raise this need further. Identified areas include creating control of the time consumption of different subsections and determine the scope of different moments in advance – two things which require both planning tools and experience feedback in the system on how much time the different sections may take. Another

prioritised area is the ability to conduct different parts of the evaluation in parallel. Other areas include introducing an electronic application system and streamlining documentation and archiving.

4.7 Control and prioritisation is important for handling evaluation within the deadlines

In most cases the assessment of the risks of the products for the environment and health is the most time-consuming part of the evaluation process. Given the tight deadlines, several countries describe that they have been forced to find ways to streamline this part of the evaluation. Among other things, it is stated that it is necessary to prioritise time on the risks which are the most important and to disregard the less important details which can cause delays in the evaluation. The balance between what constitutes more or less important risks is not an easy question, but requires competence and experience. The countries which work actively with control in the evaluation work, such as Denmark, describe that it is essential that both the departmental management group and experienced colleagues assume an active role in this process. In Denmark, there are expert team meetings to jointly solve difficult problems and the departmental management group participates regularly in meetings to eliminate discussions on details which can cause delays.

4.8 Adapt, retain and develop competence

The conditions to adapt, retain and develop competence are emphasised as very important by the majority of the studied countries. However, the conditions vary between the organisations. In some countries the authorities do not have the opportunity to expand the workforce themselves, this primarily applies in countries where the evaluation is funded by grants. Countries such as Poland, Finland and Lithuania, describe that they do not have the opportunity to recruit new personnel despite facing problems with meeting the deadlines. In the Netherlands the authority describes that they find it difficult to retain and recruit personnel as the alternative labour market is so large and many go to the industry and evaluation institutes which the authority works with.

Several countries describe that the short deadlines and the need to steer towards the most important risks in the evaluation work require that there is experienced personnel for this. Therefore it is important to retain and develop competence within the organisations. Both the Ctgb in the Netherlands and the EPA in Denmark emphasise the importance of offering stimulating and varying tasks in order to retain personnel and at the same time develop competence of the personnel. This takes place by, among other things, involving the scientific officers in the method development and the work on the European cooperation.

4.9 Discussions on values and roles have been necessary to encourage the staff to changes

Most countries are clear that current deadlines are a difficult challenge for the authorities. In some of the countries where they clearly have taken control of the activities to meet the deadlines, questions on how long the evaluations may take have been a prioritised matter within the organisation. Many describe that for this type of activity, where scientific evaluations of risks for the environment and health shall be made, it may be difficult to delimit it in time. They do also describe that this has raised issues among concerned personnel.

The Netherlands and Denmark are open about that these questions have been the subject of a lot of discussions in each organisation, but that it was crucial to get the entire organisation to accept the changes which were considered necessary. The Netherlands describes that the organisation for one year spent time and efforts on discussions, which were open and impartial, in order to get the entire organisation to agree on the relatively significant changes that the tight deadlines entail.

4.10 Better coordination between countries within the zonal cooperation is necessary

Information sharing between countries is perceived as a problem in the evaluation process. Here there are no clear-cut examples because this challenge often lies outside their national competences. Several of those interviewed demand a more coordinated process which is managed at an EU-level.

The Danish EPA is able to meet the deadlines to a large extent and describes that several important steps have been taken in the northern zone to harmonise the evaluation process. Despite this, it is experienced that the agency's planning is impeded by delays of other member countries.

In France, it is difficult to meet the deadlines because of dependency on reports from other countries within their zone. The degree of harmonisation within the different zones seems to have progressed to different extents, and even though the northern zone has relatively good conditions, there is potential for improvement.



Box 2, SE-172 13 Sundbyberg
+46 8 519 41 100

Visitors' and delivery address
Esplanaden 3A, Sundbyberg

kemi@kemi.se
www.kemikalieinspektionen.se