



Deliverable 25:

WS 6 Synthesis completed

REBECA

Regulation of Biological Control Agents

Specific Support Action

Project no. SSPE-CT-2005-022709

Contract Start Date: 01-06-2006

Duration: 24 months

Project Coordinator: Ralf-Udo Ehlers, Christian-Albrechts-University of Kiel.

Document Classification

Title	Report of WS 6 “Balancing the Benefits and Costs of Regulating Biological Plant Protection Products”
Deliverable	25
Reporting Period	2
Contractual Date of Delivery	June 2007
Actual Date of Delivery	September 2007

Authors	Heikki Hokkanen, I. Menzler-Hokkanen
Work package	WP6
Dissemination	Public
Nature	Report
Version	1.0 Final
Keywords	Costs, benefits, trade-offs

Document History

This document is a stand-alone report based on presentations and discussion notes from the workshop held in Finland on 6-8 May, 2007.

Document Abstract

This document briefly reviews the presentations and discussions at the REBECA WS 6: “Balancing the Benefits and Costs of Regulating Biological Plant Protection Products”, held in Porvoo, Finland, 6-8 May 2007.

Table of Content

Aims of the REBECA workshop (WS6) 3

Background 3

Modus operandi of the workshop..... 4

Workshop presentations and documents 4

Session summaries 4

 Session 1: Impact of regulations on BCA research and development, and on market access..... 4

 Session 2: Benefits and trade-offs of the current regulation system in the EU..... 7

 Session 3: Environmental and health risks of different plant protection methods .. 7

 Session 4: Avoiding the trade-off effects of regulation without losing benefits 9

 Session 5: REBECA proposals for general improvements of the current EU regulation system..... 11

Annex 1: REBECA Workshop on "Balancing the Benefits and Costs of Regulating Biological Plant Protection Products"..... 12

Annex II Participants..... 14

Aims of the REBECA workshop (WS6):

- (i)** To analyse how the level of regulation impacts the development and market access of biological plant protection products (BPPPs)
- (ii)** To analyse whether the level of regulation has had an effect on the documented or suspected environmental or health hazards caused by BPPPs
- (iii)** To identify different scenarios for the environmental and health hazards caused by different plant protection measures, and how regulations affect the development of such scenarios
- (iv)** To prepare a balanced synthesis of the drawbacks and benefits of regulating BPPPs

Background:

Micro-organisms, parasitoids, predators, and natural semiochemicals possess a huge potential to control plant pests and diseases. To avoid the use of potential human pathogens in plant protection, biological plant protection products (BPPPs) need to undergo a comprehensive risk assessment, and industry is required to submit extensive dossiers on their safety. This procedure is based on rules originally developed for synthetic pesticides. Although the EU directive has been adapted to better meet the requirements of BPPPs, registration still is time consuming and capital intensive, keeping most of these safe and natural plant protection products off the market.

The EU and European consumers want biological control to replace and/or to complement the current chemical pesticides based plant protection, but if the risks of biological control are exaggerated, this forces governments to implement tougher regulations, which in turn will increase the costs. In order to substitute chemical pesticides by BPPPs, less, rather than more, bureaucratic hurdles are necessary. To promote biological control, costs related to regulation should be minimized. Alternatives to the implementation of costly traditional registration procedures developed for chemical compounds must be sought. It is vital to consider also the trade-offs in imposing strict regulation. The workshop will estimate the costs for risk assessment of BPPPs, and the costs related to countervailing risks, as well as the drawbacks of regulation, and relate these to their consequences for plant protection, farmers, consumers, and biocontrol industry. Government regulation is increasingly assessed by asking whether the benefits of regulation justify their costs. The workshop aims therefore to produce a Cost-benefit-analysis (CBA) of regulation. The result of the CBA will answer the question: Do benefits of regulating BPPPs at the current or foreseen level justify the costs of regulation? A comparative analysis will be attempted to weigh the benefits and risks related to the regulation of BCAs. The analysis will support decisions on regulation to make sure that regulation policy is driven by full appreciation of relevant risks, and that it will implement cost effective and rapid regulation procedures.

Modus operandi of the workshop

The workshop consisted of five structured Sessions with presentations and discussions, and involved working in smaller groups as well. The five main topic areas (sessions) were:

1. Impact of regulations on BCA research and development, and on market access
2. Benefits and trade-offs of the current regulation system in the EU
3. Environmental and health risks of different plant protection methods
4. Avoiding the trade-off effects of regulation without losing benefits
5. REBECA proposals for general improvements of the current EU regulation system

Workshop presentations and documents

The presentations given during the workshop are available at the REBECA website (<http://www.rebeca-net.de>). Documents arising from the workshop are working documents, which have been used in consecutive REBECA meetings and independent work within the appropriate workpackages as a basis for further development and finalising.

Session summaries

Session 1: Impact of regulations on BCA research and development, and on market access

Three presentations addressed the topic of this session.

Wyn Grant analysed and discussed the way ahead for biopesticides. Problems with pesticides such as resistance, product withdrawals, and call for zero detectable residues all imply that modern, effective pesticides should be regarded as a precious resource. Sustainable, integrated pest management (IPM) based on biological control is urgently needed, opening increasing possibilities for biopesticides. Their beneficial features include that they are often very specific, they are 'inherently less toxic than conventional pesticides' (EPA), compatible with other control agents, leave little or no residue, are relatively inexpensive to develop, and support the action of natural enemies in ecologically-based IPM. Biopesticides offer important social benefits, as compared with conventional pesticides.

In dealing with biopesticides there has been a strong tendency to consider them as 'chemical clones' rather than as biological control agents, and therefore the chemical pesticide model has been followed. With this approach a danger of ignoring beneficial ecological attributes exists, and it is difficult to evaluate their contribution to sustainability (costs & benefits) in a holistic way. On the other hand, regulation of

biopesticides is needed because being 'natural' doesn't mean it is safe: there is a need to 'set the bar high'. The costs of regulatory failure are high, as shown by the BSE episode, which cast a long shadow and stifled regulatory innovation. We need an innovative system of regulation for biopesticides that will lead to more products being placed on market.

In analysing the situation Prof. Grant identified a political maturity problem in biological control. In trying to understand dynamics of a policy arena, policy networks are an important factor. In his experience, biological control agents have the weakest network encountered (as compared with e.g. dairy industry, chemical industry, fire service policy, Premiership football etc). The lack of sophistication is explained by the facts such as: biopesticides represent a small industry largely made up of SMEs; there is a failure to appreciate 'politics of possible', and to seize 'windows of opportunity'; IBMA does not have resources of crop protection industry and is still undergoing organisational development, and that there seems to be little coalition building with environmental groups.

Governments should help new industries that bring positive public benefits related to their policy goals. While at the US Environmental Protection Agency there are 20 persons employed in the microbial pesticides branch, and 23 in biochemical pesticides branch, these resources are scarce and scattered in Europe. A vital part in efforts to arrange better conditions for biopesticides in some European countries are the pre-submission meetings, but some small firms are not taking advantage of this due to lack of information, or sheer suspicion of the regulator. An emphasis on outreach is needed, but in many countries a general outreach issue is the lack of any extension service.

Mutual recognition (EU) is another key issue in future development of the biopesticide area. The Commission admits that this is currently not working. We are supposed to have an internal market, which should help to overcome the problem of small market size. Therefore we need to support the 91/414 revision that intends to create three 'eco zones' within the EU.

Further point for debate involves the question why efficacy testing is an issue in registration? Efficacy testing could be 50% of registration costs for biologicals, but just 10% for chemicals. Chemicals can use quite small treatment plots, but biologicals need larger plots to get statistical significance because individual replicates are more variable. Efficacy trials also don't always work the first time, e.g., in one set of trials pest didn't turn up two times out of three. In contrast, while the US-EPA requires applicants to test efficacy, it does not (normally) review data unless there is a risk to human health and safety. California dropped efficacy requirement in 2006, advisers did not rely on DPR data but on field experience. DPR thought it could speed the registration process without efficacy data.

Another point, raised for debate, concerned subsidies in support of biopesticide registration. There is the IR-4 programme in the USA, whose mission is to provide safe and effective pest management solutions for growers of speciality crops. Its biopesticides programme started in 1982, and was expanded in 1994. It has funded

43 projects since 1994, amounting to \$2.85M. It also gives regulatory advice, and works closely as a partner with the EPA. Comparable pilot programs have just recently been started in some European countries (GENOEG in the Netherlands, and the Biopesticides Scheme in the UK).

The case for subsidies could be justified with the argument that biopesticides bring public benefits, and help to achieve sustainability goals. However, it may raise the question whether there a market failure that in this way can be remedied by government intervention? This considerations reflect to issue of profile and political displacement of sector.

Heikki Hokkanen reported on the first results from a REBECA survey to industry concerning issues around the registration of BPPP: registration time, registration costs, and the impact of registration on BPPP research and development within the companies. By the time of the workshop, four companies were visited and interviewed, and the survey questionnaire was sent to 52 other companies active in the BPPP area.

Data on most important products (Annex I -listed) indicate that the mean registration time for EU Annex I inclusion is 75 months, while for US-EPA registration it is 28 months. Country registrations, vary widely and range from a few months up to over 100 months, averaging around 24-36 months. Preliminary results on registration cost show that EU Annex I inclusion has cost the companies about 1890 k€; out of that 970 k€ were external costs (fees etc.). The breakdown of total costs to different kinds of tests averaged as:

- efficacy tests 21 %
- toxicological tests 43 %
- ecotoxicological studies 23 %
- other required studies 13 %

R&D expenditure by the companies remained quite constant over the years, but in proportion of turnover it declined: means were 1990: **>>100%** 1995: **83%** 2000: **39%** 2005: **14%**

Information on the impact of regulatory costs and/or time on new R&D indicates that most companies still plan to bring new BPPP into market, while several others do not plan to invest into new R&D for BPPP. Products not requiring registration, of products (ai's) which already have been registered, have priority in the R&D of these companies. Several companies indicated that they would bring more BPPP into the European market if conditions for registration were more favourable; many replied that they prefer to focus on other geographical regions where the climate for this business is more favourable (North America, Asia ...). Three companies indicated that they had shelved BPPP mainly due to registration costs/time (4 products). These companies had spent on average 200 k€ in R&D on these products by the time of deciding to discontinue their commercial development. Furthermore, several companies do not plan to initiate new R&D on BPPP under the current situation, but their plans depend on "positive results from REBECA".

Peter Lüth presented a case study of two products of Prophyta: Contans and BioAct, and discussed the feasibility and need for all the studies currently required for a biopesticide. He concluded, for example, that if there wouldn't be the hurdle created by the registration, Prophyta would have at least three further products in its portfolio: Trichoderma, Beauveria, and Metarrhizium, which could replace some more or less hazardous synthetic pesticides.

Session 2: Benefits and trade-offs of the current regulation system in the EU

This was a free-form discussion session reviewing the benefits and consequences of the current regulatory system in the EU. No formal notes were taken, but rather, the discussions fed into the outcomes of Sessions 3, 4 and 5.

Session 3: Environmental and health risks of different plant protection methods

The three presentations in this session addressed the external costs of synthetic PPPs (Hermann Waibel, Germany), risks related to BCAs (Ingeborg Menzler-Hokkanen, Finland), and misuse of plant protection products in Europe (Manfred Krautter, Germany). The aims of studying **external costs of synthetic PPP** include (i) improving transparency for stakeholders, (ii) assessing adequately the benefit cost ratio of chemical PPP, (iii) facilitating comparison with alternatives, and (iv) facilitating a move towards the social optimum of pesticide use.

The external costs of pesticides include: productivity loss (crops, animals), pollution costs (water, soil, air), environmental costs (biodiversity, wildlife), human health costs (acute, chronic), information costs (regulation, monitoring), dependency (resistance, loss of beneficials), and equity issues (failure of polluter pay principle). Assessments of the external costs of chemical pesticides from several countries around the world show interestingly that the external costs sometimes greatly exceed the purchase value of pesticides, and also that many of these assessments are incomplete in the sense that not all of the important externalities have been included. For example in Germany over 50% of the estimated external costs arise from ground water contamination – which was not included in the assessment for Thailand. In the USA the biggest monetary value for externalities was placed to bird losses – and that was not considered at all for Germany or for Thailand. One conclusion from professor Waibel's presentation was that too little studies have been carried out in this area. Case studies on external costs of pesticides should be added, previous studies should be repeated, and meta analysis of external costs should be carried out. Similarly, meta analysis of the economics of using BCA should be carried out for comparison.

Risks related to BCAs was reviewed by Ingeborg Menzler-Hokkanen, who summarised the outcomes from a series of previous REBECA workshops in 2006

addressing the question. For microbial control agents the conclusions include that (i) the risks to human health are very low, (ii) main risks are to the environment (these may be perceived rather than real for many species), (iii) there is a need to separate 'true risks' from 'perceived risks', and then identify those risks that needed to be 'regulated'. Among microbial control agents some are considered a risk because they belong to species, which has been identified as a human pathogen. However, it is often possible to distinguish between BCAs and clinical isolates with the help of modern molecular methods. These data can often indicate a phylogenetic separation of the BCAs from clinical isolates of the same species and sometimes even make possible the description of new species. Concerning botanicals BPPP the risks associated with their use may vary between very low and very high. Risks should therefore be assessed case-by-case. The discrimination of low risk substances from other substances should be the result of an assessment. Semiochemical-BPPP have low inherent toxicity and are expected to present a low risk. They modify behaviour of the pest species rather than killing them, they are more target specific than conventional insecticides, and are used at concentrations close to those in nature.

It was noted that in the workshop reports, as described above, the assessment of risk (or identification of hazard) appeared to be limited to currently available, well known products, or organisms close to market, or those that have been researched for a long time as serious candidates for commercialisation. The discussion on risks might achieve other dimensions if there would be no regulations at all, or if the regulations would be significantly more relaxed than what we currently have. Attempts to commercialise organisms which currently stand no chance would likely take place. These include e.g. pathogens which are closer to vertebrate pathogens than those currently in use or in development (e.g., entomopox viruses). The question was posed whether a less stringent regulatory system would allow the use of these products (even unrestricted use), and at what risk? There is a different approach to risk in 'western' societies, and in 'developing countries' (where do Russia, Ukraine, Cuba, Kenya, etc belong to, in this assessment? Poland?).

Misuse of plant protection products in Europe was highlighted in the presentation prepared by Manfred Krautter, Greenpeace, Germany. His data, collected from Germany in 2006 and before, revealed an alarming increase in pesticide residues on vegetables and fruit sold in German supermarkets over a 10-year period. Some of these exceeded even the acute reference dose. A large proportion of samples also indicated illegal use of chemical pesticides, as produce labelled 'Produced in Germany' contained several PPP not registered in Germany (some even chemicals that never had been allowed there). A very interesting aspect of this presentation was the ranking of supermarket chains by the level of pesticide residues in their produce. Some chains have reacted very quickly to such publicity, and have set their own standards for the produce that they will accept – much lower than the officially allowed levels.

Session 4: Avoiding the trade-off effects of regulation without losing benefits

This session included five presentations. First **Patrizia Pitton** (DG-SANCO, Unit Chemicals, contaminants and pesticides) reviewed the history and principles of regulation of BCAs in the EU, and explained the current status of reviewing active substances. Around 1000 substances existing on the market need a transition period to allow a full EU evaluation. The structure of the review programme is in 4 phases, and the deadlines originally fixed for 2003 have been extended to 2006/07 and 2008. A modified approach for stage 4 review has been adopted because “ the Commission identified the need for special measures to be adopted in relation to low-risk compounds” to reduce the risk that large number of active substances would be withdrawn for pure economic reasons. This includes 83 active substances in Group A (fatty acids, plant extracts, paraffin oils, repellents), 34 ai's in Group B (semiochemicals), 16 in Group C (microorganisms), 10 in Groups D, E, F (rodenticides, fumigants, disinfectants), and 2 in Group G (actives from new member states).

The main actions of the Commission on simplification and speed up of decision making concerning BPPP include the following principles:

- Regulation, not a directive
- Approval of active substances followed by one renewal for unlimited period of time
- Clear deadlines for evaluation and authorisation
- Identification of Low risk substances and Basic substances
- Definition of minor uses and lists of minor uses at MS level
- Simplified data protection system

Risk perception and regulation was then reviewed by **Ralf-Udo Ehlers**, Germany. He pointed out that if risks are high (probability of occurrence and magnitude) societies manage risks to reduce negative impacts. Consequently, however, if we regulate risks, we deal with risk tradeoffs – and regulation has risks as well. If we exaggerate regulation, its consequences might cause more harm than the risks which we regulate. We can only make decisions when we have information on risk, on the costs of regulation and the costs of the tradeoffs. The Commission itself has stressed that where the levels of uncertainty are high, where potential impacts are very large, and/or where those impacts may be irreversible, there are grounds for adopting a precautionary approach until such time as we have sufficient scientific knowledge to make a risk-based decision. (Communication of the COM on the PP (COM2000/1). This Precautionary Principle has often been adopted in a blanket approach, as for biological control, even when none of the stated preconditions apply. BPPP have been subjected to intense level of regulation, although there is no history of large negative impacts, and the level of certainty that the agents are safe is very high. This is in complete contradiction to the history of regulation, which has been based on documented negative impacts of chemical pesticides – after which regulations have followed.

In the next presentation **Wyn Grant** (UK) explained why the new Biopesticides Scheme in the UK was launched. The main reason was concern over the general lack of alternative control options, especially of biologicals. It was considered that the small market size for BPPP and the regulatory requirements and associated fees considerably inhibited the market development. A pilot project was introduced in June 2003 with the aim to increase availability of biological pesticides in UK. The mechanisms to achieve that included (i) improving knowledge, (ii) raising awareness of regulatory requirements and how to meet them, (iii) pre- submission meetings, and (iv) reduced fees. A “Biopesticides Scheme” was launched on 1st April 2006, and it includes four categories: Semiochemicals, Micro-organisms (bacteria, fungi, protozoa, virus), natural plant extracts, and ‘other’ novel products on case by case basis. Reduced, fixed fees are applied, and free pre-submission support and advice are provided at the early stages in product development. An internal biopesticides group has been established within the PSD to keep awareness of current issues and to disseminate information.

Anita Fjelstedt, Denmark, then presented a similar scheme for the Netherlands, GENOEG. Its aims included

1. Stimulate authorisation of natural products (fund raising, help with dossier)
2. Issue management
3. Gain more knowledge and spread knowledge to growers (excursions, seminars, website)
4. Up-to-date inventory of products of natural origin (separate good from bad products)
5. Stimulate communication and advisory service on use of natural products
6. Separate effective pesticides from non-effective pesticides
7. Be a clear signal to government and policy makers

GENOEG focussed on five pilot products of natural origin, for which data on efficacy and preferably also toxicity were available, which have a low toxicity profile, for which a successful authorisation was expected, and which was linked to a company that will defend the product. A second stage of GENOEG included more crops (both arable and horticultural), emphasised the pre-application process (selection of products, advise to applicant, preparation of argumentations), included 10 products and was subsidised by €100.000.

So far as the outcome of GENOEG 5 products have been authorised. Without the help of GENOEG the applicants would not have started. Successful help was provided during the application process (lots of discussions) - without help applications would not have been successful. Financial help was also important. During the project all parties have learned a lot: there is a need for basic sets of data; there is better use and acceptance of argumentations; increased insight in uses and risks involved; improved exchange of views and start of discussions, and a better mutual understanding.

In the final presentation **David Buffin** (UK) posed the question: Are we changing from a pesticides paradigm to an ecological pest management paradigm? His major propositions included these observations/questions: (i) Current pest management methodology is unsustainable – based on fossil fuel, stakeholders are increasingly critical, and increasing regulation, (ii) Do new UK/EU pesticide policy measures (covering biopesticide alternatives) offer greater protection for health and

environment?, and (iii) How will substitution towards less hazard be achieved in practice? Dr. Buffin pointed out that ‘regulatory science’ is the product of industrial innovation and government regulation, but judgements like ‘required burden of proof’ are political rather than scientific – not curiosity driven, or welcoming of a wide range of views. Scientific uncertainty and the pressures of decision-making lead to a forced marriage between science and policy, and science always encounters an under-critical or over-critical environment when it is linked to policy. Buffin assessed the observed developments from the pesticide policy in terms of current social science academic discourse, and then compared these with empirical data generated through interviews carried out on 46 key stakeholders with either a UK and/or EU-wide focus. Overall he found:

- Lack of public profile for biopesticides
- Many respondents resonate with natural processes; but all raised potential concerns
- Environmental benefits conflict with practical challenges of marketing biopesticides
- Difficulties fitting biopesticides into a pesticide regulatory process
- Biopesticides represent a technical response rather than a sustainable philosophy

Session 5: REBECA proposals for general improvements of the current EU regulation system

Session 5 consisted of presentations and intense discussions on ways for general improvements for the current regulatory systems in the EU for BPPP. The results of these discussions are working documents and are presented among the REBECA documents at the project website; these were later finalised for presentation at the REBECA Final Conference.

Annex 1: Programme

REBECA Workshop on "Balancing the Benefits and Costs of Regulating Biological Plant Protection Products"

Time: 6-8 May 2007
Arrivals by noon on 6 May, departures after lunch on 8 May

Location: Hotel Seurahovi, Porvoo, Finland

Programme:

Sunday 6 May

Session I: Impact of regulations on BCA research and development, and on market access

- 14:30 Welcome (Heikki Hokkanen, Finland)
- 14:40 Keynote address: Biopesticides: the way ahead (Wyn Grant, UK)
- 15:10 Survey on registration costs and product innovation (Heikki Hokkanen, Finland)
- 15:30 Structure of BCA markets and the burden of regulation for an SME (Peter Lüth, Prophyta, Germany)

Session II: Working groups: Benefits and trade-offs of the current regulation system in the EU

- 18:00 Presentation of group work results and Plenum discussion on Session II

Monday 7 May

Session III: Environmental and health risks of different plant protection methods

- 08:30 External costs of synthetic PPPs (Hermann Waibel, Germany)

09:00 Risks related to BCAs (Ingeborg Menzler-Hokkanen, Finland)

09:20 Misuse of plant protection products in Europe
(Manfred Krautter, Greenpeace, Germany)

Session IV: Avoiding the trade-off effects of regulation without losing benefits

09:40 History and principles of regulation of BCAs
(Patrizia Pitton, SANCO, Belgium)

10:00 Risk perception and regulation (Ralf-Udo Ehlers, Germany)

10:40 Why the new Biopesticides Scheme in the UK was launched
(Wyn Grant, UK)

11:00 Why GENOEG?
(Anita Fjelstedt, Denmark)

11:20 Are we changing from a pesticides paradigm to an ecological pest management paradigm? (David Buffin, UK)

11:40 General discussion

12:00 Guided walking tour: Historic Porvoo (optional) Dr. Lena Huldén

14:00 Working group session

15:30 Presentation of group work results and Plenum discussion on S IV

Session V: REBECA proposals for general improvements of the current regulation system in the EU

17:30 REBECA proposals to improve EU regulations on BPPP
(Anita Fjelsted, Danish EPA) Tuesday 8 May

Session V continues: REBECA proposals for general improvements of the current regulation system in the EU

08:30 Plenum Discussion of REBECA proposals

10:30 Final general discussion: agreement on workshop conclusions

Annex II Participants:

REBECA expert team:

Jeffrey Bale, U. Birmingham, UK
Ralf-Udo Ehlers, U. Kiel, Germany
Anita Fjelsted, Danish EPA, Denmark
Rüdiger Hauschild, GAB Consulting, Germany
Heikki Hokkanen, U. Helsinki, Finland
Ulrich Kuhlmann, CAB International, UK
Ingeborg Menzler-Hokkanen, U. Helsinki, Finland
Bernhard Speiser, FiBL, Switzerland
Olaf Strauch, U. Kiel, Germany
Hermann Strasser, U. Innsbruck, Austria
Lucius Tamm, FiBL, Switzerland

EU Commission:

Patrizia Pitton, SANCO

Regulation and/or science:

Claude Alabouvette, ENDURE, INRA, France
Erdmann Bode, BBA, Germany
David Buffin, City University London
Jean Cordier, Pôle Agronomique, Rennes, France
Wyn Grant, University of Warwick, UK
Larry Huldén, University of Helsinki, Finland
Lena Huldén, University of Helsinki, Finland
Richard Meadow, PlanteForsk, Norway
Thierry Mercier, INRA, France
Catherine Regnault-Rogier, University of Pau, France
Christopher Lythgo, EFSA
Kari Tiilikkala, MTT, Finland and EFSA
Hermann Waibel, University of Hannover, Germany

Industry:

Owen Jones, AgriSense-BCS Limited, UK
Peter Lüth, Prophyta, Germany
Marina Niemi, Verdera, Finland
Aura Parmentier, Cylnatis/Agrauxine, Panossas, France

NGOs:

Pertti Rajala, Finnish Plant Protection Organization, Finland