





**MOCK Group Exercise** 

AD - Specialists

Participant Information

# **IMPORTANT NOTICE:**

This exercise should be considered as an example of group exercise that could be used in the EPSO Assessment Centre. The problems have not been fully elaborated, but give a global overview of the type of problems you could be confronted with in a real assessment centre.

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# **ASSIGNMENT**

#### **IMPORTANT NOTICE:**

The content of the document is fictitious. While the following exercises have been derived from actual events, key details have been changed. The resulting descriptions do not reflect genuine events, nor do they represent the actual views of the Member States, Institutions or their representatives.

Participants are therefore advised to rely solely on the information presented in the exercise and not on any prior domain expertise when responding to questions.

For this exercise you will assume the role of an official in the Secretariat of the European Parliament. The documentation you need is integrated in this booklet. You will find background information on the Regulation proposed by the European Commission, and the challenges it is currently facing.

It is important that you accept the simulated situation as it is presented to you. Although in a real life situation you would have access to other sources of information and would be able to consult your colleagues, in this exercise you are limited to the information contained in the exercise documents. All participants have been supplied with some common information and some information that is specific to them. You will have the opportunity to analyse this information and then discuss it with the group. You are, however, allowed to make logical assumptions where information is missing or unclear. You may rearrange the documents in any order you wish and add remarks or make notes as necessary.

This Group Exercise aims at assessing the following competencies: Analysing and Problem solving, Learning & Development, Prioritising & Organising, Working with others, Leadership and Resilience. It does not require any previous knowledge to deal with the assignment to answer the questions.

The group has been asked to prepare a recommendation on the new Regulation concerning the placing of plant protection products on the market. The aim of the meeting is to provide the European Parliament rapporteur with answers to the following questions:

- What positions can be taken regarding the placing of pesticides on the market?
- What are the pros and cons of the different options?
- Which option would the Secretariat recommend?

On the following pages, you will find background information on the Regulation proposed by the European Commission and the objections raised. Each participant has been given some common information and some information that is specific to them. You will have the opportunity to analyse the information and then discuss it with the team. You may make logical assumptions where you think the information is missing or incomplete. Please do not designate a formal chairman for this meeting.

The exercise is structured as follows:

- You will have 15 minutes to go through the information individually to prepare for the meeting. You are allowed to make notes on the documents.
- After this preparation, the group will have 50 minutes to conduct the meeting and work out a common solution.

Please note: Today is Monday, 5 December 200X Last year was 200X-1, next year will be 200X+1

# ABBREVIATIONS USED

COM Commission document reference

Commission European Commission

COPA Committee of Professional Agricultural Organisations in the European Union

CoR Committee of the Regions
ECrA European Crop Association
EEC European Economic Community

EESC European Economic and Social Committee EFWS European Federation of Water Suppliers

EU European Union

PPP Plant protection product
WWF World Wide Fund for Nature

# **BACKGROUND INFORMATION**

On 26 July 200X-5, the Commission submitted a progress report to the Council and the European Parliament on the functioning of Directive 91/414/EEC concerning the placing of plant protection products on the market {COM(200X-5)444}. The report highlighted a number of areas where the Directive could be improved.

**The Commission** concluded in its report that reform of the current legislation was necessary in order to achieve the following:

- reinforce the high level of protection of human health and the environment;
- improve the functioning of the internal market;
- maintain and enhance the competitiveness of the EU chemical industry;
- harmonise the availability of plant protection products between farmers in different Member States;
- increase transparency;
- · avoid repetition of animal testing;
- update the procedures in particular to take account of the creation of the European Food Safety Authority.

Both the Council and Parliament, in their reaction to the progress report, called on the Commission to bring forward proposals to amend the Directive.

The Council, moreover, called on the Commission to consider rules to:

- avoid repetition of testing on vertebrates;
- protect non-professional users;
- present criteria for the approval of active substances;
- further strengthen the rules governing substances with a very hazardous profile;
- introduce a simplified procedure for low-risk substances and products.

#### The European Parliament also stressed aspects such as:

- the principle of comparative assessment and substitution;
- exclusion of substances with a very hazardous profile;
- increased transparency;
- improvement of mutual recognition by introducing product authorisation zones.

On 12 July 200X the Commission published the proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market {COM(200X)388 final}. The proposed Regulation replaces Directive 91/414/EEC and repeals Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances.

In short, the Regulation consists of the following elements:

• establishment at European Union level of a positive list of active substances<sup>1</sup>, safeners<sup>2</sup>, synergists<sup>3</sup> and a negative list of co-formulants<sup>4</sup>;

- authorisation of plant protection products at Member State level;
- compulsory mutual recognition of authorisations in Member States belonging to the same authorisation zone<sup>5</sup>;
- comparative assessment of products containing substances identified as candidates for substitution;
- specific provisions for basic substances or products containing substances of low concern;
- detailed rules on data protection and transparency;
- provisions on packaging, labelling and advertising;
- obligation to keep records and to carry out controls;
- establishment of criteria for approval of active substances, safeners or synergists.

According to the European Commission, replacing Directive 91/414/EEC with a Regulation will bring clear benefits to a number of parties:

- **Member States** will no longer have to transpose approval of substances into national legislation. Stakeholders will also benefit from clearer criteria in the legislation and the fact that the Regulation will significantly shorten the approval time for active substances by laying down strict deadlines within the process.
- For **public authorities**, the administrative procedures for authorisation of plant protection products are simplified. The impact of the new mutual recognition rules applicable to three zones will be positive for public authorities and will lead to streamlined, more efficient and faster administrative procedures. The new rules on data protection are clear and will reduce the administrative burden for industry and public authorities.
- For industry, obligatory zonal mutual recognition will bring the benefits of administrative and
  procedural simplification. The deadlines for granting authorisations are much shorter than before.
- Farmers will benefit from quicker and more harmonised availability of plant protection products.

<sup>1</sup> **Substances**: Chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

<sup>2</sup> **Safeners**: Substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the preparation on certain plants.

<sup>3</sup> **Synergists**: Substances or preparations which, while showing no or only weak activity, can give enhanced activity to the active substance(s) in a plant protection product.

<sup>4</sup> **Co-formulants**: Substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists.

<sup>5</sup> **Zone**: a group of Member States for which it is assumed that the agricultural, plant health and environmental (including climatic) conditions are relatively similar.



# MAIL MESSAGE

From: Matthew Coulson, European Parliament rapporteur

To: The Secretariat

Cc:

Date: 26/07/200X

Subject: COM(200X) 388 final

#### Dear,

On 12 July 200X, the Commission submitted a proposal for a Regulation of the Parliament and of the Council concerning the placing of plant protection products on the market {COM(200X)388 final}.

Now that the proposal has been submitted, it needs to be evaluated by various parties. Despite all the efforts that have been made to limit the risks linked to the use of pesticides and to prevent any undesirable effects, the situation is not ideal. Approval of the Regulation is therefore a high priority as unwanted amounts of certain pesticides can still be found, most often in soil and water, and residues<sup>6</sup> exceeding regulatory limits still occur in agricultural produce. Actual consumption and use of plant protection products in the European Union has not decreased between 200X-15 and the present.

These are the different parties that will need to be contacted:

- Committee on Industry, Research and Energy;
- European Crop Association;
- European Federation of Water Suppliers;
- European Economic and Social Committee;
- Committee of the Regions
- World Wide Fund for Nature;
- Committee of Professional Agricultural Organisations in the European Union.

I suggest that colleagues in the Secretariat contact the above-mentioned parties in the time they have available before the meeting on 5 December 200X, where the opinions of the parties will be discussed.

I hope that we can reach agreement quickly on the proposed Regulation.

Kind regards,

#### Matthew Coulson

<sup>6</sup> **Residues:** One or more substances present in or on plants or products of plant origin, edible animal products or elsewhere in the environment, and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction products.

Extract from the Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market {COM(200X)388 final}

#### CHAPTER II - ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

#### Article 4 - Approval criteria for active substances

(...)

- 3. The use of the plant protection products, consequent on application consistent with good plant protection practice and having regard to normal conditions of use, shall meet the following requirements:
  - (a) it shall be sufficiently effective;
  - (b) it shall have no immediate or delayed harmful effect on human or animal health, directly or through drinking water, food, feed or air, or consequences in the workplace or through other indirect effects, or on groundwater;
  - (c) it shall not have any unacceptable effects on plants or plant products;
  - (d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;
  - (e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations:
    - (i) its fate and distribution in the environment, particularly contamination of surface waters, including costal waters, drinking water, groundwater, air and soil;
    - (ii) its impact on non-target species;
    - (iii) its impact on bio-diversity.

#### Article 5 - First approval

First approval for active substances shall be for a period not exceeding ten years.

#### Article 22 - Low-risk active substances

1. An active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding 15 years, where it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment.

# Article 24 - Approval criteria for candidates for substitution

1. An active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding seven years, where other already approved active substances are significantly less toxic for consumers or operators or present significantly fewer risks for the environment, as provided for in Article 46 (1).

#### CHAPTER III - PLANT PROTECTION PRODUCTS

#### Article 39 - Mutual recognition

1. The holder of an authorisation may apply for an authorisation for the same plant protection product and for the same use in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:

(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone (Annex I); or

- (b) the authorisation was granted by a Member State for use in greenhouses or as post-harvest treatment, regardless of the zone to which the reference Member State belongs.
- 2. Mutual recognition shall not apply to plant protection products containing a candidate for substitution.

#### Article 40 - Authorisation

1. The Member State to which an application under Article 39 is submitted shall authorise the plant protection product concerned under the same conditions, including classification for the purpose of Directive 1999/45/EC, as the reference Member State.

# Article 46 - Placing on the market and use of low-risk plant protection products

- 1. Where all the active substances contained in a plant protection product are substances as referred to in Article 22 ('low-risk active substances'), that product shall be authorised as a low-risk plant protection product provided it meets the following requirements:
  - (a) the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;
  - (b) it does not contain a substance of concern;
  - (c) it is sufficiently effective;
  - (d) it does not cause unnecessary pain and suffering to vertebrates to be controlled.

These products are referred to hereinafter as 'low-risk plant protection products'.

2. An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall accompany the application with a complete and summary dossier for each point of the data requirements of the active substance and the plant protection product.

# Article 49 - Extension of authorisation for minor uses

- 1. For the purpose of this Article, minor use of a plant protection product in a particular Member State means the use of that product on a crop which is not widely grown in that Member State or on a widely grown crop to meet an exceptional need.
- 2. The authorisation holder, official or scientific bodies involved in agricultural activities or professional agricultural organisations and professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.
- 3. Member States shall extend the authorisation provided that:
  - (a) the intended use is minor in nature;
  - (b) the conditions referred to in Article 4 (3) (b), (d) and (e) are satisfied;
  - (c) the extension is in the public interest;
  - (d) the documentation and information to support an extension of use has been submitted by the persons or bodies referred to in paragraph 2.
- 4. The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation, according to the administrative procedures of the Member State concerned.

5. When Member States grant an extension of authorisation for a minor use, they shall inform the authorisation holder and request him to change the labelling accordingly. Where the authorisation holder declines, the Member States shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

- 6. Member States shall establish and regularly update a list of minor uses.
- 7. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

#### CHAPTER V - DATA PROTECTION AND DATA SHARING

## Article 56 - Data protection

- 1. Test and study reports shall benefit from data protection under the conditions laid down in this Article. The protection applies to test and study reports submitted to a Member State by an applicant for authorisation under this Regulation (hereinafter called 'the first applicant'), provided that those test and study reports were
  - (a) necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop, and
  - (b) certified as compliant with the principles of Good Laboratory Practice or Good Experimental Practice in accordance with the data requirements for plant protection products.

The period of data protection is ten years starting at the date of the first authorisation in that Member State, except in the cases referred to in Article 59. That period is extended to 15 years for plant protection products covered by Article 46.

#### Article 59 - Sharing of tests and studies involving vertebrate animals

- 1. Tests and studies involving vertebrate animals shall not be repeated for the purposes of this Regulation. Any person intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.
- 2. The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

#### CHAPTER VI - PUBLIC ACCESS TO INFORMATION

## Article 60 - Confidentiality

(...)

- 2. Only the following elements shall be considered confidential:
  - (a) the method of manufacture;
  - (b) the specification of the purity of the active substance except for the impurities that are considered to be toxicologically or environmentally relevant;
  - (c) information on the complete composition of a plant protection product.

#### CHAPTER X - FEES AND CHARGES

# Article 71 - Fees and charges

1. Member States may recover the costs associated with any work they carry out arising from obligations under this Regulation, by means of fees and charges.

- 2. Member States shall ensure that the fee or charge referred to in paragraph 1:
  - (a) is established in a transparent manner; and
  - (b) corresponds to the actual cost of the work involved.

The fee or charge may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

#### ANNEX I

#### DEFINITION OF ZONES FOR THE AUTHORISATION OF PLANT PROTECTION PRODUCTS

#### Zone A - North

The following Member States belong to this zone:

Denmark, Estonia, Latvia, Lithuania, Finland and Sweden

# Zone B - Centre

The following Member States belong to this zone:

Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Romania, Austria, Poland, Slovenia, Slovakia, United Kingdom

#### Zone C - South

The following Member States belong to this zone:

Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

The following briefing is intended only for you. The other members of the group have each received a different briefing. The instructions and background information are the same for all participants.

Participant 1

You have been gathering information from:

#### THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

In preparation for the meeting you gathered information from the European Parliament's Committee on Industry, Research and Energy, to obtain their view on the proposal for placing plant protection products (PPPs) on the market of the Union.

Despite the fact that they strongly support the proposal for a new Regulation, they have raised some important issues:

- To prevent unnecessary animal testing, the Regulation should cover vertebrates only as a last resort, where no other justified scientific methods are available. Where tests have been performed on vertebrates and the results of these tests exist, they must be shared with producers who are in the process of developing new plant protection products, in order to prevent duplication. Vertebrate tests should be replaced by alternative procedures or restricted by trying to minimise the number of procedures used on animals and refined to spare the animals from terrible suffering and pain. Therefore, the data protection accorded to tests on vertebrate animals needs to be evaluated by the Commission within seven years after the Regulation comes into force. Less stringent data protection rules will help to reduce the number of tests performed on vertebrates. The Regulation must ensure that Member States do not accept the repetition of tests and studies involving vertebrate animals. For this to be achieved, all tests and studies on vertebrate animals need to be shared so that Member States can make sure that test repetition does not occur.
- The proposal for a regulation with obligatory mutual recognition is based on the assumption that the environmental and climatic conditions within a zone are "relatively similar". However, the conditions can vary between the countries of the EU. If this proposal was accepted it would mean that a product authorised in Bulgaria, for instance, should be automatically authorised in Portugal if an application was made. Even though these two countries are located in the Southern region of Europe this does not necessarily mean that conditions are similar. The authorisation of PPPs needs to be as objective as possible, taking account of all the aspects of the country requesting the authorisation. For this reason the Committee is against the creation of zones of obligatory mutual recognition.
- Many fruits and vegetables fall into the category of 'minor crops'. For such crops, limited plant protection solutions (chemical and non-chemical) exist, even though pest pressures are notably higher. Incentives are needed to cover minor uses properly. The Committee puts a lot of effort into the development and testing of PPPs to minimise their negative effects on the environment and on human and animal health. They suggest that the data protection period for plant protection products for minor uses should be extended by 3 years in order to stimulate the development of these products and their use.
- Where other already approved substances or alternative agricultural practices or methods are significantly less toxic for consumers and operators, or present significantly fewer risks for the environment, an active substance should be approved for five years instead of seven years. The approval period for active substances, normally 10 years, should clearly be shortened for this type of substance to encourage the use of less toxic products and more effective substitution. A period of five years will have a much bigger impact on pesticide producers and encourage them to develop PPPs which have a less harmful effect or no harmful effect on the environment.

The following briefing is intended only for you. The other members of the group have each received a different briefing. The instructions and background information are the same for all participants.

Participant 2

You have been gathering information from:

## THE EUROPEAN CROP ASSOCIATION (ECRA)

In preparation for the meeting, you gathered information from ECrA, to obtain their view on the proposal for placing plant protection products (PPPs) on the market of the Union.

Despite the fact that ECrA supports the proposal for a new Regulation, they have raised some important issues:

- ECrA agrees that the period of data protection for low-risk substances in the Regulation should be 15 years. This extension of the period will promote research for and the use of more sustainable substances and products, that will be less damaging to human and animal health and the environment. The EU needs to strive for better protection of plants and crops while minimising the negative effects of the products used to this end. Therefore, given the urgent need for PPPs with a low-risk profile or at least a lower risk profile than the substances currently on the market, there should be clear and objective criteria to classify low-risk PPPs.
- ECrA goes on to say that the industry is committed to the use of alternative testing methods wherever and whenever feasible. The first choice would always be to use existing data. Agreed and validated alternative test methods, such as computer modelling, should be employed where they are available. However, these alternative methods often have shortcomings, and then the only available option is to test a substance on animals. If the Regulation is approved and animal testing has to be reduced as far as possible, there will be repercussions on the development of new substances and products. The evolution and development of new products will slow down, which will have a negative economic and environmental impact. For this reason, animal testing is necessary.
- The development of products for minor uses is necessary in order to stimulate diversity. Typically, minor uses involve the use of PPPs on crops that are grown on a small scale (minor crops), which are often high-value speciality crops. In addition minor uses can also refer to use on widely grown crops for the control of minor pests and disease. In other words, minor use is where the potential use is not sufficiently large to justify a product's registration from an applicant's perspective. The key driver for not registering products for minor uses is a lack of any economic benefit from registering them and, in particular, the associated costs of generating the data required for obtaining and maintaining regulatory approval and the potential liability incurred from those uses once approved. Incentives should be offered to promote the development and use of products for minor uses. The extension of authorisation for minor uses should also be facilitated to increase the availability of products for minor crops like fruit and vegetables. ECrA suggests that these products should benefit from data protection for an additional five years.
- ECrA agrees with the first approval period of 10 years for active substances. The EU must make sure that agricultural organisations always have access to PPPs in order to protect their yield. If an active substance needs to be revised frequently, organisations may lose access to products that contain that substance. These organisations will then need to look for replacements, which will take time, while their yield could be affected, for instance by pests.

The following briefing is intended only for you. The other members of the group have each received a different briefing. The instructions and background information are the same for all participants.

Participant 3

You have been gathering information from:

## THE EUROPEAN FEDERATION OF WATER SUPPLIERS (EFWS)

In preparation for the meeting, you gathered information from the EFWS to obtain their view on the proposal for placing plant protection products (PPPs) on the market of the Union.

EFWS welcomes the Commission's proposal, as it addresses the shortcomings of the current Directive (91/414/EEC). On the other hand, there is still a lack of clarity, some omissions, and even possible loopholes in the text of the proposal that need to be addressed:

- EFWS takes the view that the proposed introduction of zonal authorisation and obligatory mutual recognition represents a first step on the road towards complete harmonisation of authorisation in Europe. Introduction of compulsory mutual recognition of authorisations in the Member States in the same authorisation zone, along with the standard authorisation procedure at national level, will prevent the duplication of work in the Member States and make innovative, environmentally-friendly plant protection products available more quickly. EFWS proposes that mutual recognition of authorisations be made possible on a cross-zonal basis in the case of (neighbouring) states where similar climatic and agricultural conditions prevail. In order to take the climatic and agricultural conditions into account, Member States should take the final decision as to whether the PPP is authorised or not.
- EFWS sees the importance of low-risk products to diminish the effect of PPPs on the environment, but they have their doubts about the efficacy of these products. For them, lower risk will automatically imply less effective substances, resulting in products that are less effective at protecting plants. This will not only affect cultivation, through a reduction in yields, it will also have an impact on intra-European competitiveness and Europe's global competitiveness, which will have major economic repercussions. If certain products are promoted by a Regulation while others, available elsewhere in Europe and on other continents, are no longer available in the EU, then EU countries will import these other products from outside the EU either because of a shortage of such products or because of the lower quality of the products available in the EU. Low-risk products should demonstrate efficacy equivalent to that of other products. The most effective way to promote low-risk active substances is to grant authorisations free of charge. This will also affect the EU's exports. If there is a shortage, fewer products will be exported and other countries will not accept products of lower quality.
- EFWS does not agree with the first approval period of 10 years for active substances. Active substances can be approved when they meet the criteria set in Article 4. But what if they show negative effects only after one or two years? There is no doubt that substances should be tested for a number of years, since in some substances certain elements only become active after a period of time. Water purification costs will be significant in the case of higher residue levels in groundwater and surface water. Who will pay for this? EFWS would refer to the case of asbestos, the dangers of which were not known at the time of its approval. For years it was used in the construction industry for its strength, durability, insulating characteristics, and low price, but eventually it had to be removed from all buildings because of the significant health risks. Altogether, more than 10 million people have died from exposure to asbestos.

The following briefing is intended only for you. The other members of the group have each received a different briefing. The instructions and background information are the same for all participants.

Participant 4

You have been gathering information from:

# THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE (EESC) AND THE COMMITTEE OF THE REGIONS (COR)

In preparation for the meeting, you gathered information from the EESC and the CoR to obtain their view on the proposal for placing plant protection products (PPPs) on the market of the Union.

#### **EESC**

The EESC does not support the proposal in the following area:

• The approval period of 7 years for active substances, where other already approved substances or alternative agricultural practices or methods are significantly less toxic for consumers and operators, or present significantly fewer risks for the environment, is unacceptable. EESC argues that these products have undergone the same testing procedures as any other substance, so they cannot see why these substances should not be approved for the same period as 'safer' substances. Otherwise the substances in question should not be authorised at all!

#### CoR

The CoR welcomes the European Commission's proposal:

- The CoR would like to suggest that the data protection period be lengthened for those products that extend their label to minor uses. Data protection should also cover data supplied to third parties when they have obtained an extension for minor use.

  Also as for as minor uses are concerned requesting authorization is often of little exercisis.
  - Also, as far as minor uses are concerned, requesting authorisation is often of little economic interest for the farming industry. To ensure that agricultural diversity is not jeopardised by a lack of available PPPs, CoR considers that specific standards must be established for minor uses. By ensuring a Single Market for PPPs, the critical problems of minor uses would in part be solved, as an extension of a PPP would be possible for all products available in the European Union and not only for those available in a given Member State. Evaluation for minor uses should be a priority and should benefit from public funding when appropriate. Furthermore, authorisation holders must be encouraged to invest in minor uses.
- Although the CoR sees the advantages of obligatory mutual recognition in 3 zones (North, Centre and South), there is also a drawback. If a Member State can make a reasonable case that the use of a certain PPP will have a different effect on the environment in its territory from that in the reference Member State, it can refuse the mutual recognition of that product. Member States should take the final decision on authorisation of PPPs given that natural conditions (soil, water and climate) can differ between them, even within the same zone. Mutual recognition can only be refused on environmental grounds. Climate is the major factor likely to cause differences in pesticide behaviour. When soil temperature decreases, the absorption of pesticides by the soil increases. This may result in lower concentrations of pesticides dissolved in soil solution and floodwater, and their slower disappearance.

The following briefing is intended only for you. The other members of the group have each received a different briefing. The instructions and background information are the same for all participants.

Participant 5

You have been gathering information from:

# THE WORLD WIDE FUND FOR NATURE (WWF)

In preparation for the meeting, you gathered information from WWF to obtain their view on the proposal for placing plant protection products (PPPs) on the market of the Union.

WWF has raised some concerns and made some suggestions regarding the proposal for a new Regulation:

- In WWF's view, animal testing will need to be performed to develop PPPs that protect plants as much as possible. However, vertebrate tests should only be conducted where necessary. WWF considers that there is no need for unnecessary animal suffering to protect crops and plants. WWF, believes that validated alternative test methods, like computer modelling, should be employed as far as possible, but where those alternative methods are inadequate, vertebrate tests may be the only option. In this case, the names of the people responsible for performing vertebrate studies should be kept confidential to ensure their protection. In the past, testing staff have had paint thrown at them in protest attacks. The legislation will need to ensure that personal data are handled confidentially to minimise such attacks.
- The proposal for mutual recognition within each of the three climate zones identified has serious shortcomings. Although WWF is generally in favour of proposals for further harmonisation and reduction of the administrative burden, they are convinced that this proposal is not the right way to achieve that. The underlying assumption that "agricultural, plant health and environmental/climatological conditions are relatively similar in the Member States concerned" does not hold, at least not for the environmental compartments 'groundwater', 'surface water' and 'soil'. These conditions vary greatly within each of the zones, leading to the same high variation in leaching to groundwater and emissions to surface water. WWF proposes a different approach: the authorisation should be as objective as possible to take account of these environmental conditions. Member States should not be obliged to recognise an authorisation decision of another Member State. Member States should simply be obliged to give serious consideration to the arguments for the decision taken by another Member State in the same zone.
- The WWF considers the approval period of seven years acceptable for active substances where other already approved substances or alternative agricultural practices or methods are significantly less toxic for consumers and operators or present significantly fewer risks for the environment. Although such active substances have gone through the same procedure as any other, they should not be approved for the same period as 'safer' substances. This is a good way to promote the use and development of less toxic substances, while acknowledging the effort that has gone into developing the active substances in question.

The following briefing is intended only for you. The other members of the group have each received a different briefing. The instructions and background information are the same for all participants.

Participant 6

You have been gathering information from:

# THE COMMITTEE OF PROFESSIONAL AGRICULTURAL ORGANISATIONS IN THE EU (COPA)

In preparation for the meeting, you gathered information from the COPA to obtain their point of view on the proposal for placing plant protection products (PPPs) on the market of the Union.

- Although COPA recognises the efforts made by the Commission and considers the creation of zones as a positive step, they believe that the ultimate objective should be the creation of a single zone and are, therefore, clearly in favour of an EU-wide harmonised authorisation system for placing plant protection products on the market. Market segmentation on a zone-by-zone basis will distort competition. To prevent any possible administrative burden on those Member States that need the authorisations for PPPs most, COPA believes it would be worthwhile trying to simplify the authorisation system and improve coordination between Member States.
- The COPA does not agree with extending the authorisation of PPPs to cover minor uses. Typically minor uses involve the use of PPPs on crops grown on a small scale (minor crops), and these are often high-value speciality crops. Additionally, minor uses can include the use of PPPs on major crops to control minor pests and diseases. The use of these products will be concentrated in certain areas because of the specific nature of the crop, for instance an apple crop. Such crops need a specific climate, type of soil and groundwater, with the result that there will be substantial pesticide use in these areas. These areas will need particular measures to reduce the impact of PPPs. If, after a certain period, it transpires that some PPPs have a negative effect on the environment, the effect will be highly concentrated in these regions. This high concentration will contaminate the groundwater, with consequent effects on local rivers. Cleaning up the rivers will be a major task and will inevitably affect the natural environment. The cost will also be very substantial.
- The problem COPA sees with low-risk substances is that PPPs containing them will presumably be less efficient. COPA represents the interests of agricultural organisations. If these substances are less effective on plants and crops, this will have substantial repercussions on cultivation and yield. Agricultural organisations will suffer major losses if the PPPs they use do not protect their yield. This could be catastrophic for imports and exports. There would be lower volumes available for export to other countries in the world, and yields might also be of poorer quality. In addition, companies in the EU would tend to import food products from outside the EU because the price would be lower, while supply would be higher and products would be of better quality. The economic impact of the Regulation will be significant.