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#### Note Verbale

The Permanent Mission of the Federal Republic of Germany to the Office of the United Nations and to the other international Organizations in Geneva presents its compliments to the Office of the High Commissioner for Human Rights and refers to the letter from the Special Rapporteur on the right to food regarding the questionnaire to prepare annual report on the implications of the widespread use of pesticides on the right to food, dated 12 October 2016.

The Permanent Mission of the Federal Republic of Germany has the honour to transmit herewith the response to the *questionnaire to prepare annual report on the implications of the widespread use of pesticides on the right to food* provided by the Federal Government of Germany to the UN Special Rapporteur.

The Permanent Mission of the Federal Republic of Germany to the Office of the United Nations and to other International Organizations in Geneva avails itself of this opportunity to renew to the High Commissioner for Human Rights the assurances of its highest consideration.

Geneva, 7 December 2016

To the

Office of the High Commissioner for Human Rights

PalaisWilson

Geneva

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#### 0. General preliminary remarks

Germany's agricultural and horticultural sector has a self-sufficiency of about 80 % for food production. The production of cereals has a self-sufficiency of about 110 % (average of the years 2011-2015), which means that Germany covers national food security and significantly contributes to global food and feed security. This only can be maintained and ensured by efficient agricultural and horticultural production systems. Integrated Pest Management (IPM), including the use of plant protection products is one of the necessary means to protect plants and crops against diseases, pests and nonparasitic disorders, to reduce yield losses and secure a sufficient quantity and high quality of food and feed. This also includes avoiding mycotoxins (caused by infection by plant pathogens) in food and animal feed. Reducing yield losses by plant protection in the field therefore importantly contributes to improved regional and global food supplies thus positively affecting the right to food. Beyond that, the protection of stored products is of great importance for food security especially in developing countries. Moreover, reducing yield losses and yield risks due to plant pests by plant protection has an important impact on food prices, thus enabling people to purchase enough healthy food.

The EU, including Germany, aims to ensure a high level of protection of both human and animal health as well as the environment with the current legislation on pesticides, applying the precautionary principle. At the same time it aims to maintain food security and the competitiveness of agriculture.

In the EU and its Member States, pesticides are divided into two legal categories: plant protection products (use on agricultural crops, <a href="http://ec.europa.eu/food/plant/pesticides en">http://ec.europa.eu/food/plant/pesticides en</a>) and biocides (use to protect human or animal health, <a href="http://ec.europa.eu/health/biocides/policy/">http://ec.europa.eu/health/biocides/policy/</a>).

The following answers refer to plant protection products only, if not otherwise mentioned."

### 1. Please list any laws (both domestic and international) that are being enforced by your Government to regulate the use of pesticides

#### National law:

Plant Protection Act and associated Ordinances: Plant Protection Use Ordinance, Plant Protection Products Regulation, Ordinance Governing Specialist Qualifications in Plant Protection, Regulation on Plant Protection Equipment, Regulation on Aerial Application of Plant Protection Products, Bee Protection Ordinance, Ordinance on the placing on the

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market and the sowing of seeds for winter cereals treated with certain plant protection products.

Hazardous substances in general (including plant protection products and biocides) are regulated by the Hazardous Substances Ordinance, which stipulates strict requirements for handling and working with hazardous substances to protect human health and the environment.

In addition, regulations on other areas of law such as legal regulations relating to water, nature protection, chemicals, genetic engineering, hazardous substances, waste, transport or food, aim to reduce possible risks arising from plant protection products.

#### EU law:

- Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
- Regulation (EC) No 1107/2009 on placing plant protection products on the market
- Regulation (EU) No 283/2013 setting out the data requirements for active substances
- Regulation (EU) No 284/2013 setting out the data requirements for plant protection products
- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products

In its development cooperation programmes, Germany takes on a particular responsibility when procuring and applying plant protection products. Germany observes strictly international regulations (such as the IFC performance standards and the World Bank safeguards) and national laws of the partner country.

2. The use of pesticides has had detrimental effects not only on the environment but also on human health, both from direct and indirect exposure. What are the successful and unsuccessful measures taken by your Government to prohibit, ban, restrict and phase out pesticides that are harmful to human health?

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Plant protection products may only be placed on the market or used if they are authorised. The comprehensive authorisation procedure in Germany is based on EU regulations and aims to ensure a high level of protection for humans, animals and the environment, including surface water and groundwater.

In the EU, Regulation (EC) No 1107/2009 stipulates that only plant protection products can be placed on the market which contain active substances that are approved on EU level. If an active substance is not approved, a phase-out period is fixed for national authorisations of plant protection products containing this substance.

EU approvals for active substances, as well as national authorisations for plant protection products, are issued only for a specified period. After expiration, a renewal of the approval/authorisation has to be applied for. EU and national authorities evaluate each application according to uniform principles, taking into account the state of the scientific and technical knowledge.

Authorisations and approvals can be re-evaluated at any time if there are indications, e.g. in the light of new scientific and technical knowledge or monitoring data, that the necessary requirements are no longer met. As a consequence, approvals/authorisations may be modified or revoked. This has happened e.g. in 2007, when the authorisations of plant protection products with the active substance tolylfluanid have been revoked in the EU because it might react with ozone to form harmful nitrosamines during drinking water treatment. Another example are POE-tallowamins that have been banned for use in glyphosate containing plant protection products after they had been identified as undesirable co-formulants.

According to Article 24 of Regulation (EC) No. 1107/2009, active substances which meet the criteria in Annex II No. 4 of this Regulation are classified as candidates for substitution. These active substances shall be only approved for a period not exceeding seven years.

In developing countries, German development cooperation follows the principles of Integrated Pest Management: use of pesticides is limited to exceptional situations where alternative treatments would not be effective, the least hazardous products are applied, a classification of the active ingredients with regard to the hazard classifications and an assessment of the risks of their application under the conditions of partner countries is conducted, selected products are applied properly and in accordance with regulations.

3. Some particularly exposed or vulnerable groups such as children, pregnant women, farmers, farm workers, indigenous peoples and migrant workers, are at greater risk to the effects of pesticides due to higher exposure or increased sensitivity. Please explain the efforts undertaken by your Government to prevent and mitigate detrimental impacts of pesticides on the health of these vulnerable groups.

Regulation (EC) No 1107/2009 aims at ensuring a high level of protection of both human and animal health and the environment, taking into account especially vulnerable groups of the population such as pregnant women, infants and children. Examples of this are the application of uncertainty factors in the derivation of specific toxicological limit values and the use of consumption data for children in the exposure assessment. The uniform principles for evaluation and authorisation of plant protection products are laid down in Regulation (EU) No 546/2011. Furthermore, hazard-based cut-off criteria, especially regarding substances toxic for reproduction and endocrine disruptors, are being implemented in the human health risk assessment.

The Plant Protection Act demands that plant protection products are used in accordance with good professional practice. This includes, for example, that the use of plant protection products is limited to the minimum amount considered necessary, that products are selected which are most suitable for the respective situation, that suitable and reliable equipment is used, and that remaining spray and rinsing fluid are properly disposed of.

According to Article 12 of Directive 2009/128/EC, the use of plant protection products is to be minimised in areas intended for the general public or used by vulnerable groups (pregnant or nursing women, unborn infants and children, the elderly). Such areas include public parks and gardens, sports and recreation grounds, school grounds and children playgrounds and the vicinity of healthcare facilities. The application of a plant protection product in such areas is only allowed if the product has been specifically approved for use on areas intended for the general public.

Non-professional users are allowed to buy and use only those plant protection products which are authorised for home gardening. These products must meet specific requirements as to the properties of the active substances they contain and of the product itself, dosage form, dosing and packaging.

According to Article 5 of Directive 2009/128/EC, professional users (including farm workers), distributors and advisors must have access to appropriate initial and additional training which provides them with sufficient knowledge on the proper use of pesticides. Training subjects

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are specified in Annex I of this Directive. By 2013, certification systems had to be established by all EU Member States. In Germany, this requirement is implemented by the German Plant Protection Ordinance Governing Specialist Qualifications. It should be noted that initial training of professional users of plant protection products has been mandatory in Germany since 1987.

The Federal Institute for Risk Assessment (BfR) maintains a list of poisoning information centres in central health care facilities throughout Germany, where the public can request information. An application available for mobile devices provides valuable information especially in poisoning cases of children. Germany has established a notification system for poisoning incidents. Every physician who is asked to treat or assess the consequences of health disorders caused by chemical substances or products (e.g. pesticides) is obliged to submit the main details of the poisoning incident to the Poison and Product Documentation Centre at the BfR (<a href="http://www.bfr.bund.de/en/notification">http://www.bfr.bund.de/en/notification</a> of poisoning incidents-10143.html). The BfR informs producers and traders in case of health impairments by their products.

Residue behaviour and toxicity of active substances and plant protection products are tested based on harmonised data requirements published in Regulations (EU) No 283/2013 and 284/2013. Both Regulations are accompanied by a Commission Communication describing guidelines and guidance documents to be used, most of them are published by OECD and are internationally agreed. In order to minimize effects by residues of plant protection products in food, national diets and specific properties of infants and children (e.g. "hand-to-mouth" behaviour, higher metabolism rate per body weight) are taken into account in the evaluation.

In developing countries, German Development Cooperation follows instructions for handling as set in the FAO/WHO International Code of Conduct on Pesticide Management and the supporting technical guidelines, in particular those relating to packaging/labelling, storage, application and disposal of surplus pesticide (remaining quantity) and empty containers of pesticides developed by the FAO/WHO Joint Meeting on Pesticide Management (JMPM). In addition, Germany observes strictly international regulations such as the IFC performance standards and the World Bank safeguards.

4. Have any studies been conducted, with the support of your Government, using disaggregated data to differentiate and detect impacts on above-mentioned vulnerable groups?

The following food surveys have been / are still being conducted in Germany in order to collect consumption data among German children and thus provide an actual and comprehensive data basis for Germany's youngest consumers. Thus, it is possible to conduct the exposure assessment for the most vulnerable sector of the population:

- VELS study (consumption survey of food intake among infants and young children)
- BfR-MEAL study (meals for exposure estimation and analysis of foods): Germany's first total diet study (<a href="http://www.bfr.bund.de/cm/349/bfr-meal-study-nominated-substances.pdf">http://www.bfr.bund.de/cm/349/bfr-meal-study-nominated-substances.pdf</a>)
- KIESEL study: <a href="https://openagrar.bmel-forschung.de/receive/openagrar mods">https://openagrar.bmel-forschung.de/receive/openagrar mods</a> 00021782

In 2015, a survey was initiated dealing with the protection of workers and bystanders. Another survey investigates the use of plant protection products by amateur users (home gardening). Both studies are conducted within the National Action Plan (see answer to question 7).

The protection of vulnerable groups of consumers is achieved by using different consumer groups for risk assessment (see answers to questions 3 and 7).

5. Considering that States have an obligation to implement the right to information on hazardous substances, please give examples of how your Government has ensured that pesticide users and consumers are informed of the hazards and risks of pesticides used in food production?

Each plant protection product authorised in Germany is subject to classification and labelling in accordance with Regulation (EC) No 1272/2008. The classification and labelling is a component of the proposed instructions for use of the plant protection product. With every authorisation for a plant protection product, the BVL imposes a set of restrictions and directions for use to avoid risks and to guarantee safe use (see answer to question 7). These have to be printed on the product label and instructions for use, and can also be retrieved from a public online database (www.bvl.bund.de/psmdb).

The Plant Protection Ordinance Governing Specialist Qualifications stipulates that traders and professional users of plant protection products must hold a certificate to ensure they can use these products safely. This certificate is valid for three years and may be prolonged if

further training offered by certified institutions can be accounted for at regular intervals. The agricultural extension services of the German Federal States are responsible for the certificate system. They also offer training and advice for professional und non-professional users of plant protection products.

The Federal Office of Consumer Protection and Food Safety (BVL) maintains a web site where consumers, traders and users can find information on how to properly sell, buy, use and dispose of plant protection products (<a href="www.bvl.bund.de">www.bvl.bund.de</a> > plant protection products). Specific material is available e.g. for non-professional users ("home and garden" users) and users of parallel trade products.

The "Agrarinformationsdienst" provides a variety of information and training material for the general public and agricultural users in the fields of agriculture, food and feed (<a href="https://www.aid.de">www.aid.de</a>).

Risk communication is an important task of the BfR. Timely information and answers to questions are provided to the public at large regarding human health risk assessment of plant protection products. Current examples of successful risk communication measures can be seen in the measures taken regarding glyphosate and endocrine disruptors.

6. Please provide any good practices that your Government has initiated to assess, monitor, prevent and mitigate the risks of exposure to hazardous pesticides, and what further efforts could be undertaken.

Guidance documents and evaluation concepts for the improvement of human health risk assessment are continually developed and refined, e.g. to account for combined effect of components of mixtures.

Maximum residue levels (MRL) are laid down in Regulation (EC) No 396/2005. According to chapter V, a Community co-ordinated control program and national control programs took place. In both cases, monitoring and enforcement of the rules are conducted by Federal State laboratories. Results of the national food surveillance system are reported to the BVL, which reports on the national findings (<a href="http://www.bvl.bund.de/nbpsm">http://www.bvl.bund.de/nbpsm</a>, in German). In addition, the results of all EU Member States, Norway and Iceland are reported in a standard format to the European Food Safety Authority (EFSA), which is responsible for compiling the Annual Report on Pesticide Residues. This report is publicly available (<a href="https://www.efsa.europa.eu/en/topics/topic/pesticides">https://www.efsa.europa.eu/en/topics/topic/pesticides</a>).

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Consumer risk assessment is done at two stages. It is a prerequisite for MRL setting. Only MRL that are safe for consumers can be established. For this reason EFSA has collected intake data from Member States and set up the so-called Pesticide Residue Intake Model, using WHO guidance to calculate short-term and long-term intakes. The model includes data from different Member States and different consumer groups. The model can be found on EFSA webpage. Member States and EFSA are continuously working on an update of intake data. Currently Germany has set up a new study: The MEAL Study (meals for exposure assessment and analysis of foods) is the first Total Diet Study for Germany (see answer to question 4). It determines which substances occur in which concentration in foods after processing and preparation.

During MRL enforcement every exceedance of a MRL, after subtraction of measurement uncertainty, will be subject to further investigations. The food concerned needs to be withdrawn from the market and distributors are subject to a fine. If, in addition to an exceedance of a MRL, the acute reference dose (ARfD) is also exceeded, a message is sent to the Rapid Alert System, a warning system within the EU to prevent that unsafe food is distributed on the Common Market. A similar system is established by WHO (INFOSAN). Both systems cooperate to a certain extent.

The BVL established the task force "Residues of plant protection products in food" in 2010. The results of the national food surveillance system and the residue control of the food industries are exchanged in annual meetings. The aim is to identify reasons for MRL exceedance and to prevent exceedance of MRL in the future. The percentage of MRL exceedances has been continually reduced.

On national level, there is a close cooperation and information exchange between the Federal Office of Consumer Protection and Food Safety (BVL), the agricultural extension services of the German Federal States, environmental authorities conduction monitoring (in surface water and groundwater), the foodstuff control (exceeding of MRL's), farmer associations and non-governmental organisations:

The Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL) organises annual meetings with stakeholders to establish and update an action plan to prevent the illegal trade and use of plant protection products.

According to the German Plant Protection Control Program, the agricultural extension services inspect traders and users of plant protection products to make sure that only authorised products are sold, and that products are used according to the label. This includes the analysis of plant protection products to verify their composition and the absence

of relevant impurities. The results of national monitoring programs in surface and groundwater are reviewed by the Federal Environmental Protection Agency (Umweltbundesamt, UBA) and BVL. This can result in an explanation of findings conducted by the authorisation holder of a plant protection product. The BVL can oblige authorisation holders of plant protection products to conduct post-registration monitoring studies to investigate the impact of a use or the effect of risk mitigation measures.

Additionally, Germany has transposed the Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides by setting up the National Action Plan for the Sustainable Use of Pesticides (see answer to question 8).

In order to avoid pesticides in raw water for the abstraction of drinking water, most of the federal states of Germany have issued protection zone ordinances. These differ slightly between states, but in essence they enable the limitation of pesticide use in the catchment of drinking-water wells or reservoirs – with different levels of limitation relating to proximity to the point of water abstraction. A German national standard (DVGW W 101 and W 102) also describes how to delineate such protection zones, and this is widely implemented.

In developing countries, German Development Cooperation promotes the use of Integrated Pest Management. An IPM Guideline is giving orientation to all programmes.

7. Gaps and weaknesses in international and national regulatory systems allow the use of pesticides that are unsafe, even when used legally and per instruction, on the market. Please provide examples of good practices initiated by your Government in building effective protection frameworks governing the production and use of pesticides.

First-time authorisations of plant protection products are granted for a maximum of 10 years in Germany by the Federal Office of Consumer Protection and Food Safety (BVL). Products may only be used for specific combinations of crop and harmful organism.

After expiry, an authorisation has to be reapplied for and a new assessment is performed in keeping with current scientific and technical knowledge. The authorization is granted for 15 years. The BVL may re-evaluate an authorisation at any time if relevant new information, e.g. on potentially harmful effects, becomes available (see answer to question 2).

Together with authorisation, the BVL imposes restrictions and directions for use to avoid risks and to guarantee safe use, e.g.:

- whether the product may be used by professional or non-professional users
- safety advice for classification, labelling, packaging and disposal
- mandatory use of personal protective equipment for mixing, loading and application
- re-entry period for treated areas
- safety intervals between the last application and the harvest.

These measures have to be printed on the product label and directions for use. The agricultural extension services of the German Federal States are responsible for enforcement and control of these measures. They collaborate closely with the BVL to prevent infringements by traders and users.

Furthermore, the Plant Protection Act demands that plant protection products are used in accordance with good professional practice. This concept includes, for example, limiting the use of plant protection products to the minimum amount considered necessary, selecting the products which are most suitable for the respective situation, using suitable and reliable equipment and disposing of remaining spray and rinsing fluid properly. The BMEL has summarised the principles of good professional practice in a publication. Further advice for those who use plant protection products near residential areas, gardens or roads and paths has been published in a leaflet by the BMEL.

The Regulation on Plant Protection Equipment stipulates the demands on equipment which is used to apply plant protection products. The Julius Kühn-Institute, Federal Research Centre for Cultivated Plants (JKI), tests and inspects plant protection equipment regarding to its drift reducing features. It is obligatory to have the equipment tested and approved of according to the voluntary procedure. Furthermore, the JKI tests plant protection equipment as to its rate of saved products and enters the satisfactory equipment into the section "reduction" of the register of loss reducing equipment.

Professional users, traders and advisors are subject to initial and additional training as stipulated by the Plant Protection Ordinance Governing Specialist Qualifications (see answer to question 3).

Customs services of the German Federal States control the import of plant protection products to ensure that only authorized products are placed on the market. German

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authorities also contribute to an OECD working group to prevent illegal traffic of plant protection products.

The trade and use of plant protection products are inspected within the German Plant Protection Control Program. The methods used and results are published at <a href="http://www.bvl.bund.de/psmkontrollprogramm">http://www.bvl.bund.de/psmkontrollprogramm</a> (in German only).

In developing countries, German Development Cooperation promotes the application of Integrated Pest Management. The use of substances that are classified by WHO as moderately hazardous (WHO Hazard Class II) is limited to educated personnel by taking strictly all precautions (occupational safety and user protection). These requirements (strict protection measures and correct use) are usually not met by small-scale farmers in developing countries and emerging economies. Thus, these products can only be procured for small-scale farmers after appropriate training. Without protection equipment users should not have access to these products, to ensure the necessary protection for users and environment.

8. Please provide examples of efforts supported by your Government to reduce the use of pesticides in agricultural food production, including by incentivising ecological methods of pest control and agro-ecology (including training programmes, provision of financial support, etc.). Please indicate how successful and how widely implemented such efforts have been to date.

Several national programmes to reduce the risks resulting from the use of plant protection products date back until 2002 (<a href="https://www.nap-pflanzenschutz.de/en/about-the-national-action-plan/history/">https://www.nap-pflanzenschutz.de/en/about-the-national-action-plan/history/</a>). Since 2009, the National Action Plan was further developed to implement Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides. The main goals of the National Action Plan include:

- Risk reduction: Use and application of plant protection products is associated to certain
  risks to ecosystems. A 30 percent risk reduction is projected by 2023 (baseline is the
  1996-2005 average). Interim results of an analysis with the risk indicator SYNOPS show
  for 2014 a distinct reduction of the risks arising from insecticide and fungicide use and a
  moderate risk reduction for herbicides compared to the reference period.
- Reduction of limit-exceeding maximum residue levels: Compliance with residue levels is crucial for food quality. The goal is to reduce limit-exceeding levels in all food product

groups of domestic or non-domestic origin below 1 percent by 2021, based on representative monitoring results.

- Limiting the use of Plant Protection Products: Reduction of the use intensity to a 'necessary minimum' which is required for economic crop production. The 'necessary minimum' is calculated based on the information obtained from the Network of References farms, where farmers hand in their anonymized pesticide use records (since 2007). Experts from the official agricultural extension services of the Federal States and scientists of the JKI research institute assess the 'necessary minimum' and calculate the intensity of pesticide use. The results are published in annual reports (<a href="http://pub.iki.bund.de/index.php/BerichteJKI/article/view/6271">http://pub.iki.bund.de/index.php/BerichteJKI/article/view/6271</a>) and provide valuable evidence of pesticide use in Germany as well as information for issues for future training of and advice to growers.
- The introduction and further development of plant protection measures and integrated pest management. To further improve growers practice, ensure a sustainable production and reduce the risks associated to the use of pesticides, the different sectors of agricultural and horticultural production as well as other non-agricultural associations have developed or are developing crop- or sector specific guidelines for integrated pest management. Those guidelines are developed according to Art. 13 (Directive 2009/128/EC). They cover the general principles of integrated pest management (IPM, Annex III of Directive 2009/128/EC) and provide tailor-made crop- or sector specific measures, foremost focusing on prevention, alternatives to pesticides as well as the use of decision support and prognosis systems.
- In addition, a model project of demonstration farms on IPM (<a href="https://demo-ips.iki.bund.de/">https://demo-ips.iki.bund.de/</a>; https://www.nap-pflanzenschutz.de/en/practice/demonstration-farms/) has been initiated in 2011. The pilot farms are set up to implement and test new methods of IPM and demonstrate these to other farmers, advisers and the public. Advisors and knowledge transfer methods individually support the demonstration farm activities.
- Optimizing information of the public: Knowledge sharing of benefits and risks of plant protection including applications of chemical plant protection products.

A number of sub-goals and related measures, also including the protection of ground- and surface water as well as biodiversity, supports each of these main goals. All stakeholders meet annually to discuss the progress and results of these measures. In addition, a number of technical sub-groups for water protection and biodiversity have been constituted to further discuss and propose more detailed measures and actions.

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For more information on the National Action Plan see <a href="https://www.nap-pflanzenschutz.de/en/practice">https://www.nap-pflanzenschutz.de/en/practice</a>.

In developing countries, German Development Cooperation promotes the use of Integrated Pest Management. An IPM Guideline is giving orientation to all programmes. All available pest control techniques are carefully considered and emphasise is given to the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.

- 9. Please share any information regarding court decisions or on-going litigation in relation to the detrimental effects of pesticides, in particular in relation to the right to food.
- 10. Please provide any additional information you believe would be useful to understand the challenges confronting your Government in its efforts to prevent and mitigate adverse impacts of pesticides on human health, the right to food, and the environment.