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POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY **A**

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EU's Pesticide Risk Assessment System: The Case of Glyphosate

Study for the ENVI Committee

DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

EU's Pesticide Risk Assessment System: The Case of Glyphosate

Brussels, 24 May 2016

PROCEEDINGS

Abstract

This report summarises the presentations and discussions of the workshop on the “EU’s pesticide risk assessment system: the case of glyphosate”, held at the European Parliament in Brussels on Tuesday, 24 May 2016. The aim of the workshop was to provide background information and advice for the Members of the ENVI Committee on the effects of glyphosate on human health.

During the first part of the workshop, the EU policy context and the state of play of the issue were presented. An update on the environmental effects of glyphosate on biodiversity was also given. Moreover, the status of the precautionary principle, a legal principle which underpins the use of this substance, was discussed.

The second part of the workshop focused on the challenges and options based on the available research and evidence. The different findings of the IARC and EFSA were presented. In particular, the different methods of the evaluation, as well as the difference between hazard assessment and risk assessment, were covered during this session. Furthermore, the ongoing ECHA’s evaluation of glyphosate, which is being carried out under the CLP Regulation, was illustrated.

Finally, the perspectives from civil society and doctors were also taken into account. While the divergences during the sessions showed how polarised the issue is, it was outlined that a decision on the glyphosate matter would be crucial in order to bring to an end a situation of uncertainty.

This workshop and the respective document were prepared by the Policy Department A at the request of the Committee on Environment, Public Health and Food Safety.

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LIST OF ABBREVIATIONS

AGRICAN AGRiculture and CANcer cohort study

CJEU Court of Justice of the European Union

CLH Classification and labelling

DG SANTE Directorate General for Health and Food Safety

EC European Commission

ECHA European Chemicals Agency

ECL European Cancer Leagues

EFSA European Food Safety Authority

EU European Union

GBHs Glyphosate-based herbicides

GHS UN Global Harmonised System

GTF Glyphosate Task Force

HEAL Health and Environment Alliance

IARC International Agency for Research on Cancer

JMPR Joint Meeting on Pesticide Residues

MEP Member of European Parliament

MRLs Maximum residue levels

NHL Non-Hodgkin lymphoma

NOAEL No-observed-adverse-effect-level

PP Precautionary principle

RAC ECHA's Committee for Risk Assessment

TFEU Treaty on the Functioning of the European Union

UBA German Environmental Agency

UNCED United Nations Conference on the Environment and Development

WHO World Health Organisation

EXECUTIVE SUMMARY

On 24 May 2016, the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament held a workshop on “EU's pesticide risk assessment system: the case of glyphosate”. The workshop was hosted by Mr Alojz PETERLE (MEP), co-chair of the Health Working Group within the ENVI Committee.

Mr PETERLE opened the discussion by highlighting that the aim of the workshop was to provide clarification on the alleged carcinogenic properties of glyphosate. He introduced the context of the debate on glyphosate, one of the most widely used pesticides in the EU, and in particular the different findings of the International Agency for Research on Cancer (IARC) as well as the European Food Safety Authority (EFSA) studies. Mr Peterle also stressed the relevance of the issue for European Union citizens.

Ms JULICHER, Director for “Food and feed safety, innovation” (DG SANTE) started the first part of the workshop, which focused on the EU legal and policy context, by setting out the overall regulatory framework. In particular, she explained the process of the active substance approval at EU level, and the subsequent plant protection product authorisation at Member State level. She concluded that the EU regulatory system is robust and that the steps taken to authorise a substance such as glyphosate are solid and well-based.

Dr PIEPER of the German Environmental Agency (UBA) then spoke about the environmental risks of glyphosate. After briefly explaining how the risks stemming from glyphosate are assessed, Dr Pieper outlined the direct and indirect effects of glyphosate on biodiversity. Stressing the need for mitigation measures in order to approve glyphosate, she underlined that successful risk regulation is possible, reasonable, and essential to protect biodiversity.

Dr DOUMA of the Asser Institute concluded the first part of the workshop by addressing the precautionary principle. In particular, he explored the origins of the principle, how it was codified in EU law and how it was later employed in the Commission Communication of 2000. Finally, by recalling two examples of European Court of Justice case law, Dr Douma concluded that the EU institutions are obliged to either apply the precautionary principle where the risks are uncertain or to provide adequate motivation if it is not applied.

Part Two of the workshop was opened by Mr TARAZONA of EFSA. He started by outlining public health assessments for pesticides, namely the difference between hazard identification, hazard characterisation and potency, exposure assessment and the risk for consumers. Mr Tarazona then introduced the results of EFSA's assessment concerning the glyphosate case, underlining that a public health assessment is not only triggered by carcinogenicity, but also other toxic effects. He stated that the Toxicological Reference Values proposed by EFSA offer a high level of protection, and also cover the effects considered relevant by IARC. On the basis of these results, EFSA concluded that no health concerns for European consumers could be linked to the use of glyphosate.

The second speaker of this panel was Dr GUYTON from the IARC. She started by explaining the methodology of the IARC assessment on glyphosate and stressed that the evaluation was fully in line with accepted principles. Dr Guyton then referenced several studies on glyphosate, noting that there is sufficient evidence of cancer in animals and strong evidence that it causes DNA damage. She concluded that glyphosate fits into Group 2A, and therefore is probably carcinogenic to humans. Finally, she stressed that the IARC does not make policy recommendations; however, she outlined some future steps for glyphosate assessment.

The final speaker of the second session was Dr DE BRUIJN of the European Chemicals Agency (ECHA). He started by explaining the relevant regulatory framework for ECHA's ongoing glyphosate evaluation, essentially the CLP Regulation. He then clarified the different phases of the evaluation, noting that it is currently in its infancy and that results are not expected before the end of 2017. Finally, Dr de Bruijn specified the next steps of the process, which include public consultations and opinion development.

Opening the third part of the workshop focusing on perspectives from civil society and doctors, Dr LEBAILLY (AGRICAN) gave an overview of the health risks associated with the use of glyphosate in agriculture, especially with regard to the French experience. Dr Lebailly presented various statistics from the AGRiculture and CANcer (AGRICAN) cohort study, which analysed enrolment and causes of death for the 2005-2009 period. He noted that measuring pesticide exposure levels is difficult, as is identifying those individuals affected.

The next speaker, Prof Dr BAUR (EOMSociety) gave an overview of options based on clinical daily practice from his perspective as a doctor treating patients affected by pesticides. He identified a link between glyphosate exposure and various human health effects. Moreover, he made a parallel between the cases of asbestos and glyphosate, stressing that the lessons learnt from the asbestos pandemic should be used when deciding on the future of glyphosate.

The final speaker for the afternoon was Ms JENSEN (HEAL). She first highlighted the concerns stemming from the use of glyphosate, such as a longer persistence in the environment, its carcinogenicity, as well as the possible endocrine disruption. Ms Jensen recalled the probable long term public health consequences associated with glyphosate, including an increased risk of developing non Hodgkin Lymphoma. Finally, she affirmed that approving glyphosate is against EU law and the public will, noting that individuals cannot choose to avoid glyphosate exposure.

The floor was opened for questions twice during the afternoon. This allowed for a lively and informed discussion, with various perspectives aired, highlighting how contentious and polarising the issue of glyphosate is.

In his closing remarks, Mr PETERLE thanked the speakers for their presentations representing the different viewpoints and expressed appreciation for the lively discussion. He then stressed that while glyphosate is currently a cause of concern for European citizens, the EU is still divided on this issue. Consequently, he hoped that viable alternatives to glyphosate can be found. Finally, he urged the European Commission to take a decision on this topic, also taking into account the position of the European Parliament.

1. LEGAL AND POLICY BACKGROUND

Glyphosate is one of the most widely used herbicides. It is an active substance used in agriculture and horticulture, primarily to combat weeds that compete with cultivated crops. Glyphosate-based herbicides (GBHs) - common trade name "Roundup" - were first sold to farmers in 1974 by Monsanto, an US agricultural company. Since then, the volume of GBHs applied has increased approximately 100-fold and has been widely used by gardeners and farmers.

According to EU law, plant protection products, among which glyphosate is included, fall within the scope of Regulation (EC) No 1107/2009¹. This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the EU. Pursuant to Article 4 of the Regulation, an active substance shall be approved in accordance with Annex II, which sets out the procedure and criteria for the approval of the substances in question. Point 3.6.3. of Annex II specifies that *"[a]n active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B"* ².

Part of the scientific community has claimed that the use of glyphosate can be harmful for human health, resulting in the ban or restriction of the use of glyphosate in large parts of Europe. In 2015, the International Agency for Research on Cancer (IARC), the specialised cancer agency of WHO, classified glyphosate as *"probably carcinogenic to humans"* (Group 2A)³. The criteria used by the IARC for Group 2A are comparable to those for Category 1B in Regulation (EC) No 1272/2008. According to the IARC, the categorisation is used *"when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. Limited evidence means that a positive association has been observed between exposure to the agent and cancer but that other explanations for the observations (called chance, bias, or confounding) could not be ruled out. This category is also used when there is limited evidence of carcinogenicity in humans and strong data on how the agent causes cancer"*.

The IARC report generated a significant response among environmental groups, who called for a total ban of glyphosate⁴. Moreover, 1.4 million people signed an online petition, organised by Avaaz, against the use of glyphosate⁵. Monsanto, on the other hand, which manufactures glyphosate-resistant GM crops for use with Roundup, took a strong position against the IARC report and filed a legal challenge in the United States⁶.

In April 2015, the European Food Safety Authority (EFSA) received a mandate from the

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products.

² Regulation (EC) No 1107/2009, Annex II, point 3.6.3. Moreover, in the event that the authorisation is granted, the competent authorities in Member States shall refer to the guidance document on pesticide residue analytical methods provided by the European Commission (SANCO/825/00 rev. 8.16 16/11/2010), available at: http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/guide_doc_825-00_rev8_en.pdf (accessed March 2016).

³ IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides, <https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf> (accessed June 2016).

⁴ Greenpeace.org, Glyphosate licence renewal suspended in light of health concerns, 8 March 2016, available at: <http://www.greenpeace.org/eu-unit/en/News/2016/Glyphosate-licence-renewal-suspended-in-light-of-health-concerns/> (accessed March 2016).

⁵ https://secure.avaaz.org/en/monsanto_dont_silence_science_loc_eu/?pv=180&rc=fb (accessed March 2016).

⁶ <http://www.monsanto.com/iarc-roundup/pages/default.aspx> (accessed March 2016).

European Commission to consider the findings of the IARC and to carry out a peer review as part of the legal process required to renew authorisation of glyphosate use in Europe⁷. Contrary to the IARC report, the results of the research conducted by EFSA claimed that glyphosate is “*unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008*”⁸. The opposite results of the findings generated a fierce debate between EU and UN agencies over whether glyphosate should be considered to cause cancer or not⁹.

The findings of the EFSA were supposed to be used by the European Commission in deciding whether or not to keep glyphosate on the EU list of approved active substances. However, on Tuesday 8 March 2016, the EU Standing Committee on Plant, Animal, Food and Feed (PAFF Committee), tasked with the decision for a new 15-year licence for glyphosate, failed to reach a decisive majority, with the strongest opposition coming from Italy, France, Sweden and the Netherlands¹⁰. One month later, on 13 April 2016, the European Parliament voted on a non-binding resolution urging, *inter alia*, the Commission to renew the marketing approval of glyphosate for just seven years, instead of fifteen, and for professional use only¹¹.

Furthermore, on 16 May 2016, another WHO body (the Joint Meeting on Pesticide Residues, JMPR) issued a report that concluded that glyphosate is “*unlikely to cause cancer in people via dietary exposure*”¹². On 18 and 19 May, a meeting of the PAFF Committee ended again with no vote over renewing the controversial herbicide. The European Commission now has to decide by 30 June 2016 whether or not to keep glyphosate on the EU list of approved active substances. If not, after a six-month grace period, Member States will be obliged to remove it from the market. Finally, the European Chemicals Agency (ECHA) is also currently dealing with an evaluation of glyphosate, but the results are not expected until the end of 2017.

⁷ The peer review was required by the Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission, available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0380> (accessed March 2016).

⁸ EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302, https://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf (accessed June 2016).

⁹ Reuters.com, EU to defer decision on safety of weed-killer ingredient: sources, 7 March 2016, available at: <http://www.reuters.com/article/us-health-eu-glyphosate-idUSKCNOW922K> (accessed March 2016).

¹⁰ EurActive.com, EU delays glyphosate decision amid cancer uproar, 09 March 2016, available at: <http://www.euractiv.com/section/science-policy/news/eu-delays-glyphosate-decision-amid-cancer-uproar/> (accessed March 2016).

¹¹ European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D044281/01 – 2016/2624(RSP)), <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2016-0119+0+DOC+XML+V0//EN> (accessed June 2016).

¹² Joint FAO/WHO Meeting on Pesticide Residues, Summary Report, 16 May 2016, <http://www.who.int/foodsafety/jmprsummary2016.pdf> (accessed June 2016).

2. PROCEEDINGS OF THE WORKSHOP

2.1. Introduction

2.1.1. Welcome and opening

MEP Mr Alojz PETERLE, Co-Chair, ENVI Health Working Group

The workshop was opened by the chair, Mr Alojz PETERLE (MEP), who welcomed all participants. He briefly set out the purpose of the workshop, and noted that the concerns related to the use of pesticides are increasing from an agricultural perspective but also with regard to its effects on human health, the environment and biodiversity. Glyphosate is omnipresent, and high concentrations of the pesticide can be found in water, soil and food, as well as in human bodies. People ingest glyphosate mainly from food, including cereals, which have been treated with a glyphosate based herbicide just prior to harvest. Mr Peterle noted that a recent study by the Heinrich Böll Foundation¹³ concluded that more than 99% of people in Germany have traces of the compound in their urine.

One of the questions that Mr Peterle hoped to have answered during the workshop was what could be considered a "safe limit" for chemicals such as glyphosate. While glyphosate has approval from regulatory bodies worldwide, there are growing concerns about its possible adverse effects. In particular regarding carcinogenicity, but also regarding its impacts on Parkinson's disease, infertility and birth defects. Mr Peterle referred to the study of the IARC in 2015, which concluded that glyphosate is a probable human carcinogen. On the contrary, Mr Peterle noted that the EFSA has concluded that the glyphosate is not likely to be carcinogenic to humans and the evidence does not support the classification with regard to its carcinogenic potential.

These different results produced by EFSA and IARC have left many citizens concerned. According to Mr Peterle, citizens and civil society organisations reacted to both reports and many letters were received. Newspapers are full of articles with contrasting messages, and debates in the European Parliament have created a polarising atmosphere. Politics can become scientised, and science politicised. Mr Peterle stated that the different methods employed have led to a clash between the agencies, and - in Mr Peterle's view - it is this divergence which requires additional attention. Mr Peterle said he was hoping to hear that there are signs of progress in corporation between both relevant agencies that would help all to better understand the different results.

Mr Peterle outlined the Commission's approach, with a proposal for a blanket reauthorisation of glyphosate submitted to the Parliament. The resolution calling for restricted use was adopted during a plenary session last April. The European Parliament is, however, calling for a more comprehensive independent review of the chemical's health effects and urging the Commission and the EFSA to disclose all of the scientific evidence behind its positive opinion. The Commission has now put forward a proposal that would re-authorise glyphosate for nine years with no new restrictions. In response, about 150 thousand citizens signed a petition calling for glyphosate to be banned and protests were organised ahead of the vote. The Standing Committee on Plants, Animals, Food and Feed met again on 19 May 2016 to vote on whether to extend the authorisation of glyphosate or not. Again, after failing to come to an agreement this past March, the Committee could

¹³ Monika Krüger, Andrea Lindner, Johannes Heimrath, Heinrich Böll Foundation, Nachweis von Glyphosat im Urin freiwilliger, selbstzahlender Studienteilnehmer – „Urinale 2015“, available (in German) at: <http://www.urinale.org/wp-content/uploads/2016/03/PK-Text-Handout.pdf> (accessed June 2016).

still not get a majority of countries for or against the authorisation. Since it was obvious that no qualified majority would be reached, a vote was not held.

Mr Peterle explained that now the European Chemicals Agency is to review the possible carcinogenicity of glyphosate, but that progress will not be finalised before the end of 2017. After outlining the agenda, Mr Peterle then duly gave the floor to the first speaker, Ms Sabine Juelicher, Director for Food and Feed Safety, Innovation of DG SANTE of the European Commission.

2.2. Part I: EU Policy Context and Latest Developments

2.2.1. Glyphosate: the process and latest EU policy developments

Ms Sabine JUELICHER, European Commission, DG SANTE, Director for Food and feed safety, innovation

Ms JUELICHER started her presentation by reinforcing the relevance of the topic, especially with regard to how farming is viewed in the future and the general use of pesticides. Her presentation focused on the process, highlighting that the process used is more comprehensive than the question of reauthorisation and the conditions under which a particular substance is used. She also stressed that the EU legislation making up the overall framework for plant protection products (commonly known as pesticides) is comprehensive and unique worldwide. As a result, pesticides and plant protection products are amongst the most heavily regulated products/chemicals in the chemicals' area.

Ms Juelicher began by explaining the EU legislation including Regulation 1107/2009 concerning the placing of plant protection products on the market. She mentioned how this covers the production phase and the risk assessment steps which have to be undertaken before any active substance can be approved, as well as the use phase (in particular the Directive on Sustainable Use of Pesticides). She also noted there are provisions on, for example, the use of machinery, and comprehensive legislation on maximum residue levels (MRLs), which ensure that pesticide residue in food and feed do not result in a risk to human health, even under a scenario of lifelong consumption.

Ms Juelicher then focused on the two steps of the process for approving glyphosate, the first one being the EU assessment of active substances for possible approval or re-approval. Under this step, and under the relevant legislation, active substances are assessed for their safety. Once this safety level has been established, they are approved for their use at EU level and added to a positive list. Therefore, unless comprehensive data has been brought forward to demonstrate the safety of the substance, it is not placed on a positive list, and it can subsequently not be used.

The second step addressed by Ms Juelicher is under the Member States' responsibility. Once the active substance (glyphosate) has been approved, it can be used to make a final product which is sold commercially to farmers and other individuals. This final product must be approved by Member States, on the basis of EU legislation. Ms Juelicher referred to the following two examples of final products that include glyphosate: Roundup, produced by Monsanto, and Touchdown, produced by Syngenta. Again, this is an authorisation process and may only be granted for those uses of the product which were demonstrated to be safe following a second step of risk assessment of the product.

Going back to the first step, Ms Juelicher explained how the one decision taken at EU level would apply to all 28 Member States. The approval for an active substance for the first time is usually set for 10 years, yet glyphosate was first approved in 2002. Next, a review is required, and after that the standard timeframe would usually be 15 years. The

difference between the initial approval and renewal is the context of the data dossier. Ms Juelicher noted that for a renewal, outdated information is replaced, while other information (such as the boiling point of a substance) would be retained.

With regard to glyphosate, the renewal is only being talked about now due to Regulation 1107, which came into force in 2009. The subsequent new stricter criteria were to be used for reauthorisations, and for that reason the approval was prolonged together with other substances.

Ms Juelicher then explained how the re-approval is being undertaken in the case of glyphosate. In this case, Germany is the rapporteur Member State in charge of the re-approval, and tasked with evaluating the data dossier. Germany then produces a draft assessment report which is then transmitted to the European Food Safety Authority. EFSA then publishes a summary dossier of the documents, results, and draft assessment report, which are displayed online. The public are invited to comment on the draft. At the same time, a peer review is initiated, meaning all Member States, through their scientific bodies, review the draft assessment report and together draft a conclusion on whether the active substance can be expected to fulfil the assessment criteria laid down in legislation. The process for glyphosate is still ongoing, and EFSA has received a very high number of public comments. For this reason, the deadline for the Rapporteur Member State and EFSA has been prolonged in order to take these into account.

Ms Juelicher then moved to the next stage, the approval of the product by Member States. As glyphosate has already been on the market for some time, there are a number of products that have already been approved by Member States. At this stage Ms Juelicher stressed that Member States are able to apply risk mitigation measures when developing a national strategy on the use of pesticides in their territory, for example prohibiting the use of herbicide on a sealed surface, developing training programmes for users and distributors of the pesticide, or banning its use in critical areas for environmental and health reasons.

Ms Juelicher finished her presentation by quickly addressing the setting of MRLs. She stressed that in the EU there is a very comprehensive, official monitoring programme for pesticide residue, for which around 80 thousand samples are taken annually, including 10 thousand samples alone for the testing of glyphosate in food products. This means they have a very comprehensive overview about the presence of this product in food, and therefore know that this product, in particular, has very few exceedances of the MRLs.

2.2.2. Regulating environmental risks: The case of glyphosate

Dr Silvia PIEPER, German Environmental Agency (UBA), Senior Scientific Officer - Ecotoxicology

Dr PIEPER started her presentation by asking the question “why is glyphosate also an environmental case?” She explained that glyphosate is a broad spectrum herbicide, which means that it kills all plants and not just the target organism, and therefore may have unintended consequences. Because it is broad-spectrum, it has a range of uses, including for “all crops”, pre and post planting, in forests, grass lands, parks, gardens, essentially almost everywhere. Risks include harm to other plants, vertebrates, and biodiversity via the destruction of food webs.

This does not necessarily mean the active substance cannot be approved. Normally the condition of approval includes risk mitigation measures. There are well-known risk management option mitigation measures available, for example no-spray buffer zones in fields acting to protect the environment. With glyphosate there are also indirect effects, as

well as direct effects on non-target plants, by way of a disruption in the whole food web, resulting in insufficient insects for birds and animals. Dr Pieper noted that birds have been seen to decline only in agricultural areas, and to manage this, new mitigation measures are needed. This could include conservation flowering strips in fields, which are unsprayed and non-crop to support biodiversity and the food web.

Dr Pieper then presented some statistical evidence supporting the loss of biodiversity, especially birds, due to agricultural impacts, as well as results of mitigation measures. She stressed that such mitigation measures for the approval of glyphosate should not be compulsory but rather a precondition for the use of glyphosate, and such preconditions as risk mitigation measures are normal in the risk regulation of pesticides. In other cases, a vegetated buffer strip is required to mitigate runoff, and if it is not there, the pesticide cannot be used.

Therefore, a successful risk regulation of glyphosate is possible, given that the identified risks are high with regard to biodiversity and food web interactions. To finish her presentation, Dr Pieper stressed that the successful risk mitigation of glyphosate is possible and necessary, if the substance is to be approved under current legislation.

2.2.3. Status of precautionary principle in EU risk management

Dr Wybe DOUMA, T.M.C. Asser Institute, Senior Researcher

Dr DOUMA started his presentation by outlining that the precautionary principle (PP) first came up during the 1980's in Germany, and that it was created in order to deal with potential risks¹⁴. Subsequently, the Germans introduced the PP at international level by including it in the non-binding text of the North Sea Conferences. The text stated that the PP was necessary to avoid potentially damaging impacts of substances, even when there is no scientific evidence to prove a causal link between emissions and effects. From there, the principle was then imported to the global level through the United Nations Conference on the Environment and Development (UNCED) held in Rio de Janeiro in 1992. The PP ended up in the final declaration as Principle 15 which states the following: *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*.

From that moment, the PP was also codified in the EU Treaty. Dr Douma noted that while all the other environmental principles were already included in the EU Treaty in 1987, the PP was only inserted in 1993. Currently, the PP is embedded in Article 191 of the Treaty on the Functioning of the European Union (TFEU). Dr Douma pointed out that: i) the PP is inserted in the EU Treaty without a definition; ii) it has a binding legal status; and iii) the PP is also included in the EU secondary law, for instance in the REACH Regulation and in the Plant Protection Products Regulation.

Furthermore, in 2000, seven years after the PP was codified in the EU treaty, the European Commission (EC) issued a Communication¹⁵ which explained how and when to use the PP. Dr Douma highlighted that the communication was the result of the division within the EC on this issue and, as a consequence, the final result is not always convincing. For instance,

¹⁴ James Cameron and Juli Abouchar, The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment, 14 B.C. Int'l & Comp. L. Rev. 1 (1991), <http://lawdigitalcommons.bc.edu/iclr/vol14/iss1/2> (accessed June 2016).

¹⁵ European Commission, Communication from the Commission on the precautionary principle (COM/2000/0001 final), available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52000DC0001> (accessed June 2016).

the Communication did not introduce an EU definition of the principle in question. It is important to note that, supported by the case law of the European Court of Justice, the European Commission stated that although the PP is embedded in the environmental protection part of the Treaties, it is a principle of a broader importance as it also refers to the protection of humans, animals and plant health.

Dr Douma emphasised that there is a difference between the descriptions in the Communication and the Rio Declaration. In particular, the former does not stress that there is a threshold of serious or irreversible damages; thus, in principle the PP can apply to all potential damages. Moreover, the Communication makes a distinction between a prudent approach in the risk assessment phase and applying PP in the risk management phase. Dr Douma also stressed that when the PP is used, the reversal burden does not always have to be applied. However, the Communication says that in individual cases this might be necessary, for instance when a substance like pesticide is a priori (potentially) hazardous issue. In addition, the Communication specifies that following the application of the PP, the subsequent risk management decisions can be: i) either no measures (for the time being); or ii) precautionary measures (warning, ban, etc.). Finally, the Communication stresses that in these circumstances a maximum amount of transparency is needed.

As far as the Court of Justice of the European Union (CJEU) is concerned, in its case law it is confirmed that the PP is a legally binding principle and, consequently, it must be used for potential risks related to the environment, humans, animals, and plants. The CJEU also set out specific circumstances under which the PP can be used, and explained how in certain situations the legislator still has a margin of discretion to adopt measures. However, Dr Douma believes that, according to the most recent case law of the CJEU, in certain circumstances, the EU legislator is obliged to adopt precautionary measures.

In order to prove its statement, Dr Douma then illustrated two recent case laws of the CJEU: the Neptune Distribution case, regarding the salt level in mineral waters, and the Pillbox 38 case, regarding E-cigarettes. According to the Neptune, the EU legislature "*must take account of the precautionary principle, according to which, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent*". Moreover, according to the Pillbox case "*the identified and potential risks linked to the use of electronic cigarettes [...] required the EU legislature to act in a manner consistent with the requirements stemming from the precautionary principle*".

Finally, Dr Douma concluded that considering the TFEU, the CJEU case law, and Commission guidelines on the application of the PP:

- The EU institutions must apply the PP in cases where there is uncertainty as to existence or extent of risks;
- The PP justifies the adoption of restrictions; and
- A decision not to adopt restrictions must be carefully motivated, identifying exactly what is known and the gaps in knowledge, as well as setting out in detail why potential risks did not warrant adoption of restrictions.

2.2.4. Questions & Answers

Axel SINGHOFFEN (EP Green Group advisor) asked two questions to Ms JUELICHER. Firstly, he remarked that the EU Regulation refers explicitly to the precautionary principle and explicitly empowers the Commission to take action in case there is a potential health risk, and yet there are uncertainties. In this regard he underlined that the controversy between IARC and EFSA generated uncertainties, therefore the precautionary principle is fully

applicable in the glyphosate situation. He also wondered why the European Commission, considering that the European Parliament have asked for a restriction for the non-professional use of glyphosate, has not proposed any explicit precautionary measures in its proposal.

Secondly, he remarked that indeed pesticides are developed to kill pests; however, glyphosate is a non-selective broadband killer which kills not only plants, but also bacteria, fungi, algae. In this regard he recalled that the glyphosate may have adverse impacts on biodiversity, as explained by Dr PIEPER, and that the EU law foresees that pesticides should not have such an effect. Therefore, he wondered why the European Commission thinks that the use of this non selective broadband killer complies with the provision of the law.

Stuart AGNEW (MEP), first asked for further clarifications about the renewal of the licence for glyphosate. He also stressed that if glyphosate will be banned, or if the precautionary principle will be applied, this will have serious consequences for farmers in England who need the substance question in order to safeguard their food stocks in the long term.

Mr PETERLE asked the audience whether there are alternatives to glyphosate or not, stressing that he believes that other alternatives exist.

Ms JUELICHER (European Commission) first emphasised that in order to establish whether the precautionary principle should be applied, it has to be established whether there is or not a level of uncertainty in the current situation. She then remarked that the WHO website provides an explanation about the difference between the work carried out by the IARC and the one carried out by the Joint Meeting on Pesticide Residues (JMPR). In particular, she underlined that the processes carried out by the two WHO bodies, the hazard assessment and the risk assessment, are complementary and not contradictory. Furthermore, since the JMPR, which is in charge of the risk assessment like the EFSA, came to the same conclusion as the latter, which is that under a certain level the use of glyphosate does not pose any risks for human health, there is no situation of uncertainty at the moment that would trigger the application of the precautionary principle.

With regard to the non-professional use of glyphosate, Ms Juelicher recalled that some Member States have banned the non-professional uses of glyphosate. As regards the effects on biodiversity, Ms Juelicher stressed that there are mitigation measures that can be adopted in order to mitigate the risks on the environment. As far as the alternatives of glyphosate are concerned, Ms Juelicher added that while there are alternatives, it is understood that from the risk profile they can be even less favourable than the existing products. Finally, Ms Juelicher added that should there be new scientific knowledge coming up, this will be certainly taken into account.

Dr DOUMA stated that the original 15 years' reauthorisation of glyphosate after being reduced to only nine years already represents an adoption of a precautionary measure. Therefore, he believes there is a presumption under which the precautionary principle should be applied. As for the alternatives, he stressed that they certainly have to be taken into account; however, this must not imply that in practice every single alternative should be investigated and only after full scientific evidence can a precautionary measure be applied. A situation of this kind, he stressed, would hinder the essence of the precautionary principle and would prevent its useful and practical effects.

2.3. Part II: Challenges and Options Based on Available Research and Evidence

2.3.1. Glyphosate: from the identification of hazards to the evaluation of risks

Mr Jose Vicente TARAZONA, European Food Safety Authority (EFSA), Head of Unit (Pesticides)

Dr TARAZONA presented the conclusions of the European Food Safety Authority on glyphosate. In this regard, he recalled that the EU public health assessment for pesticides is based on four different steps. The first step is hazard identification, which determines whether a chemical is capable of producing adverse effects on humans. The second step is called hazard characterisation and analyses which doses produce the adverse effects. The third step is the exposure assessment which measures the level of exposure which is expected for the citizens. Finally, the last step measures the *actual* level of risk - and not the hazard - for EU consumers. (

Dr Tarazona also highlighted the different roles of the different institutions involved. He stressed that with regard to the hazard identification phase, on the one hand, at EU level, the responsible institutions are the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA). On the other hand, at international level, the responsible bodies are the International Agency for Research on Cancer (IARC) and the Joint Meeting on Pesticide Residues (JMPR), which both operate within the framework of the World Health Organisation (WHO). As far as the other three steps of the assessments are concerned, namely hazard characterisation, exposure assessment, and risk for consumers, Dr Tarazona observed that at EU level the only responsible institution is EFSA, whereas, at international level, the only responsible body is the JMPR.

After the general overview, Dr Tarazona explained in detail how glyphosate was assessed by EFSA. He pointed out that during the hazard identification procedure, EFSA assessed all the available evidence in humans and animals, with a specific focus on tumour induction mechanisms. At this point Dr Tarazona underlined that chemicals may either initiate a tumour, or promote a tumour after the initiation, or to have only secondary effects at very high doses. Dr Tarazona then reiterated that, according to the EFSA assessment, the only available evidence with regard to the carcinogenicity and genotoxicity of glyphosate is that it is able to produce only secondary effects and only at very high doses that are not relevant for humans. He also stressed that the JMPR's recent report¹⁶ supports this conclusion.

Subsequently, Dr Tarazona tackled the hazard characterisation phase. In this regard, EFSA considered all adverse effects relevant for humans, also those not leading to the classification. As a result, the potential genotoxicity of glyphosate was also part of the assessment. Dr Tarazona also recalled that the aim of this phase is to measure which level of exposure leads to adverse health effects and especially to identify the so called "critical effects". The latter are defined as the adverse health effects occurring at the lowest level in all available evidence. Therefore, if the risk assessment suggests these critical effects are prevented or confirmed, it can be assumed that all the other effects will also be prevented or confirmed. So the general principle of the hazard characterisation is to first select the adverse health effects that are relevant for humans, then identify the lowest doses (critical effects), and apply the risk assessment for those effects in order to cover all the relevant effects for humans.

¹⁶ Food and Agriculture Organisation of the United Nations, World Health Organisation, Joint FAO/WHO meeting on pesticide residues, Geneva 9-13 may 2016, Summary report, available at: <http://www.who.int/foodsafety/jmprsummary2016.pdf?ua=1> (accessed June 2016).

Dr Tarazona also presented the summary of the EFSA evaluation with regard to the hazard characterisation phase. He explained that carcinogenetic effects that were considered relevant by the IARC appeared in the EFSA evaluation at doses spanning from 1000 to 4800 mg/kg body weight (per day) during long term exposure. Other effects (e.g. rodent reproductive no-observed-adverse-effect-level (NOAEL), dog short-term NOAEL, mice overall NOAEL, etc.) occurred at lower doses, spanning from 100 to 300 mg/kg body weight. With regard to the critical effects selected by EFSA, they appeared in rabbits at doses higher than 50 mg/kg body weight. EFSA applied the standard uncertainty factor to protect humans at the value of 50 mg/kg body weight. Thus, EFSA's recommendation is that the level of exposure of people should never be 0.5 mg/kg body weight per day. This value is 200 times lower than the effects that trigger the classification for carcinogenicity of glyphosate that were considered relevant by the IARC.

Dr Tarazona then moved to the third phase of the public health assessment of pesticides, namely the exposure assessment. The aim of this phase is to measure the actual level of exposure of the European citizens. He stressed that with regard to glyphosate, EFSA has three different pieces of information. Firstly, the information included in the EFSA conclusion of the representative crops. EFSA covered all the representative uses in the conclusion, including experimental studies that measure the level of glyphosate that are expected in foods as well as exposure assessments according to the diets of EU citizens. Secondly, the information contained in the exposure based on actual measurements in food where glyphosate is detected in about 60% of all food commodities for which it is assessed. Thanks to those measurements, it is possible to carry out an actual assessment in order to establish the level of exposure. And finally, the information stemming from the human biomonitoring data, which allows for the detection of the *actual* level of exposure of EU citizens. For instance, there have been several studies measuring the level of glyphosate in the human body through the analysis of urine. This process allows for the estimation of what is the expected level of risk for every person by comparing the concentration levels of glyphosate in the human body which are considered safe. Moreover, Dr Tarazona mentioned that EFSA is also conducting the review of all maximum residue levels (MRLs) and authorised uses in the EU that lead to potential residues of glyphosate in food. This review will be assessed in an EFSA opinion about the MRLs for glyphosate.

Next, Dr Tarazona focused on the last phase of the EFSA evaluation: the EU consumers' risk assessment. He first clarified that in the evaluation the risk is presented as the percentage of the maximum level (notably, 0.5 mg/kg body weight per day) that EFSA recommends. Moreover, he stressed that any values below 100% are considered as no public concerns as it represents the level of exposure which is considered fully acceptable since it does not lead to any risks for the consumers.

He then illustrated the information based on which EFSA reached its conclusion. According to the information included in the representative crops, the risk is 3% for the chronic and 9% for the acute reference doses. Therefore, being way below 100%, the risk is considered as very low. Furthermore, according to the measured residues in food the actual chronic exposure is 0.6% and the acute one is 23.4% (four times below the level of risk). Lastly, according to the human biomonitoring studies, which measure the *actual* level of risk for EU citizens, the exposure to residues in food, the so called dietary assessment, is 0.1% and 8.4% for the people exposed to non-dietary rules (which are people that actually apply glyphosate products), therefore both clearly below the 100% level that should be considered as a potential issue.

Finally, Dr Tarazona concluded that:

- the public health assessment is triggered by toxic effects that are different from carcinogenicity and appear at much lower doses;
- the Toxicological Reference Values proposed by EFSA offer a high level of protection, covering also the effects that were considered relevant by IARC; and
- according to the EFSA estimations, there are no health concerns for European consumers that have been detected using three complementary exposure assessments.

2.3.2. The carcinogenicity of glyphosate

Dr Kate Z. GUYTON, World Health Organisation (WHO), International Agency for Research on Cancer (IARC), Senior Toxicologist at the IARC Monographs Programme

Dr GUYTON presented the IARC assessment of glyphosate. She first recalled that the IARC evaluated glyphosate in March 2015 as group 2A, which means “*probably carcinogenic to humans*”¹⁷. She pointed out that the classification referred to the strength of scientific evidence that glyphosate causes cancer. Moreover, she underlined that IARC did not carry out a risk assessment, but rather a hazard assessment. Dr Guyton also called attention to the two reasons according to which IARC evaluations are used as a reference worldwide. Firstly, she mentioned that all data are in the public domain and can be independently evaluated. She also stressed that this aspect is essential for transparency. Secondly, she declared that the evaluations are done by leading experts without vested interests. She emphasised that this aspect is important for independence. Subsequently, Dr Guyton stated that once an IARC classification is made, there can be a risk assessment, which is usually a quantitative estimate of cancer risks for different types of exposure. She also asserted that sometimes public health measures to protect workers and the public can be adopted.

Analysing in more detail the glyphosate evaluation, Dr Guyton underlined that the latter was done according to the IARC standard process. She explained that the scientific review process occurred over a period of about one year, the meetings took place in Lyon and were open to scientific observers and government representatives. She also stressed that IARC was pleased to have the participation of scientists from Monsanto, from industry organisations, such as the European Crop Protection Agency, as well as from academic institutions. Furthermore, Dr Guyton underlined that the IARC evaluation is a transparent process under which all the data under review can be accessed by all the meeting's participants. In addition, given the intense interest in the *Monographs*, Dr Guyton specified that IARC shared their references with other health agencies, including the EFSA. Thus, IARC accelerated the production of the fully referenced *Monographs* that are now publically available on-line for free download.

Further, Dr Guyton moved to the explanation on how glyphosate was evaluated by IARC. She stated that IARC monographs' evaluation is based on a systematic assembling review of the all publically available evidence that addresses carcinogenicity. This included about 1000 studies, including laboratory studies of animals that have been exposed to glyphosate in its formulations, studies of people that were exposed to it in their jobs, and studies of people that have been exposed to it in their communities. In the end, the *Monographs* stated more than 250 references.

¹⁷ IARC List of Classifications, Agents Classified by the IARC Monographs, Volumes 1–116: <http://monographs.iarc.fr/ENG/Classification/index.php> (Accessed June 2016).

Dr Guyton then summarised the evidence of the different types of studies mentioned above. She began by addressing the studies of cancer in humans and outlined that there were two kinds of study that were available concerning Non-Hodgkin lymphoma (NHL). The first was a case-control study which was carried out in three different regions of the world and showed increased risks of developing NHL. Moreover, Dr Guyton mentioned a different kind of study called the cohort study, the largest agricultural health study that has been done in three states in the US. This study, which is ongoing, showed no significant increase in risk based on the few cases of NHL that the scientists have observed. Furthermore, she mentioned another study that the working group undertook which is called the meta-analysis where all cases from all the studies were analysed. Dr Guyton believes that this is an objective method to combine all studies. She also mentioned that the meta-analysis showed significant increased risks of NHL in all the studies that were available. Overall, she affirmed that this led to a conclusion of limited evidence.

In addition to those, Dr Guyton referred to other studies about cancer in rodents. In particular, she mentioned two studies on the mouse where glyphosate was positive. The result was rare cancers and that is extremely important in assessing human risk. However, she pointed out that it is very challenging to detect signal from background noise. Nevertheless, there was high statistical significance that the evaluation done by the working group was fully in line with accepted principles and led to the conclusion that there was sufficient evidence of cancer in animals.

Finally, Dr Guyton summarised the glyphosate hazard evaluation and stated there were two lines of studies that contained *limited* evidence of cancer (NHL) in humans; however, she remarked that the glyphosate formulations were done in different regions at different times, and this circumstance may indicate that glyphosate was the cause of the cancer. Other studies contained *sufficient* evidences of cancer in animals. A third type of study, called 'mechanistic studies', contained strong evidences of carcinogenic causes, DNA damage and oxidative stress. As a result, Dr Guyton affirmed that all together this led to the classification of glyphosate in group 2A ("probably carcinogenic to humans").

Dr Guyton also outlined what usually happens after the IARC classification. She stated the typical risk assessment is carried out, which is normally a quantitative estimate of cancer risk with exposure. This type of assessment is helpful for understanding the level of risks and addresses different exposure scenarios (e.g. in the diet, in the job, in the communities). She also mentioned the possibility of undertaking public health actions in order to reduce exposure to workers and the general public. Dr Guyton also underlined that IARC does not make any policy recommendations. It remains the responsibility of governments and international organisations to limit exposure to substances classified as carcinogenic by IARC.

To end, Dr Guyton offers some suggestions in order to improve evaluations. Firstly, registering studies in advance; secondly, adopting clear methods for analysis and reporting; and thirdly, ensuring that all the public data are available. In the last slide Dr Guyton presented a complementary strategy aimed at prioritising pesticides for cancer hazard evaluation by using chemoinformatics, database integration and automated text mining.

2.3.3. ECHA's Evaluation of Glyphosate

Dr Jack DE BRUIJN, Director, Risk Management Directorate, European Chemicals Agency (ECHA)

Dr DE BRUIJN's presentation focused on the ongoing ECHA assessment of glyphosate under the CLP Regulation (1272/2008/EC)¹⁸. However, he reminded everyone that the harmonised classification and labelling (CLH) process¹⁹ of glyphosate was at its very early stage, therefore he could not provide too many details about the evaluation, but rather give a general overview of the process, and how the transparency of the latter will be ensured.

Firstly, Dr de Bruijn explained that the CLP Regulation implements the UN Global Harmonised System (GHS) for classification and labelling in the EU. The aim of this Regulation is to ensure a high level of protection of human health and the environment. He also added that under the CHL process the ECHA classifies the (active) substances based only on their hazardous properties. As a consequence, the CHL process cannot be qualified as a risk assessment as it does not take into account the level of exposure and the potential risk. Moreover, he underlined that the Regulation contains a high number of chemicals covered by harmonised classification and labelling (CLH) that can be found on the ECHA's website.

Dr de Bruijn then illustrated that the CLH process is made of different steps. Accordingly, the Member States or (in some cases) the industry may submit a proposal to the ECHA in order to include a substance in Annex VI of the CLP Regulation ("harmonised classification labelling of a new hazardous substance"). It has to be noted that ECHA itself cannot propose the inclusion of a substance in Annex VI. The proposal is then evaluated by the ECHA's Committee for Risk Assessment (RAC), which is a body composed of independent scientists appointed by the ECHA's Management Board based on the nominations of the Member States' Competent Authorities. This body is in charge of issuing a scientific opinion based on the proposal. After that, the European Commission has to decide whether to include the substance in Annex VI.

Dr de Bruijn underlined that the process is carried out in a transparent manner. This is ensured through the public consultation that is opened after the dossier has received the accordance check from the ECHA secretariat. During the public consultations all interested parties may provide comments which are also publically available on the ECHA's website throughout the process. Moreover, the stakeholders (industries, NGOs, etc.) have the possibility to take part in the meetings of the RAC. Finally, at the end of the public consultation, the ECHA replies to all comments received. Dr de Bruijn also remarked that, pursuant to the CLP Regulation, ECHA has 18 months to deal with a proposal. Moreover, he stressed that since 2009, when the CLH process started for the first time, the RAC has issued about 200 opinions that can be found on the ECHA's website. The majority of these opinions have been adopted by the European Commission, and, consequently, ended up in changes to Annex VI of the CLP Regulation. In particular, pesticides and biocides currently represent 60% of the revisions in annex VI.

With regard to the ECHA ongoing evaluation of glyphosate, Dr de Bruijn explained that ECHA has received the proposal from the German authority which has gone through the

¹⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF> (accessed June 2016).

¹⁹ The CLH is the process under which a Member State's competent authorities may propose a new harmonised classification and labelling (CLH).

accordance check and it is currently being revised by the human authorities. He also stressed that glyphosate is already in Annex VI of the CLP Regulation, and it is classified as a toxic substance which causes serious and high level damages. However, the German authority has requested an additional classification for specific targets organ toxicity (STOT RE) based on new data.

He also noted that the process is now at its very early stage. Currently the rapporteurs have been appointed in accordance with the REACH Regulation governing the ECHA Committees and Committee's Rules of Procedure. Moreover, the ECHA secretariat has completed the accordance check for the CLH dossier and the German authority is making the final revisions. The launch of the public consultation is planned for early June and it will last for 45 days. The human authorities will then answer to all the comments that will be provided and based on that the RAC rapporteurs will issue the opinion. The first discussion is expected in December 2016. The adoption instead is expected to take place in the RAC meetings, either in March or in June 2017, but this will depend on the amount of information that will be received through the public consultation and the scientific assessment. In addition, ECHA is also considering expert consultation meetings if necessary based on the comments received.

2.3.4. Questions & Answers

Mr Jan HUITEMA (MEP) remarked that based on the information provided in slides number 5 and 7 presented by Mr TARAZONA (EFSA), the daily intake of glyphosate to which people are exposed is 2 million times less than the dose necessary to develop its carcinogenic effects. Therefore, he stressed, while from a hazard perspective glyphosate might be considered as carcinogenic, from the risk assessment perspective, there is no significant risk for the consumers to develop cancer from the use of glyphosate. Additionally, he asked the audience why, considering that there is a consensus among scientists that glyphosate is safe, there is still a political debate about its authorisation.

Mr Stuart Agnew (MEP) supported the argument raised by Mr Huitema, MEP, by stating that there is no risk of developing any sort of cancer from the use of glyphosate. Moreover, he emphasised that while IARC designated glyphosate as "probably carcinogenic", they also classified other activities as possible carcinogenic, such as the cutting of human hair, sitting in front of the log fire, and drinking mate. He then remarked that while these activities are put on the same level as glyphosate, it is unlikely that the EU could ban them.

Mr POC (MEP) first observed the EU system of authorisation has a low sensibility and high permeability and, as a consequence, people are not able to catch the complex context of the whole influence of pesticides. For instance, he explained that glyphosate was developed as an antibiotic, and, despite the EU fighting antibiotic resistance, glyphosate, which is an antibiotic, is sprayed in agriculture. This aspect, he stressed, was not taken into account neither by EFSA, nor by IARC. Furthermore, he asserted that also the metabolic influences of glyphosate were not taken into account. Thus, he urged the audience to consider the glyphosate issue with care, not only because of its direct toxicity, but also for its other properties, such as the endocrine disrupting ones. Further, Mr POC pointed out the endocrine disrupting properties of glyphosate were also not taken into account in the evaluations.

Mr Euros JONES (European Crop Protection) reacted to the comment of MEP Mr POC by stating that the endocrine effects of glyphosate were taken into account by many countries. For instance, he recalled that the French Minister of Health claimed that glyphosate is an endocrine disruptor. Moreover, he reminded everyone that there has been an evaluation

from EFSA with regard to the endocrine effects of glyphosate, although not according to the new criteria.

Prof. David ZARUK (author of the blog "The Risk-Monger") recalled that very recently the other body of the WHO, the JMPR, concluded that glyphosate was probably not carcinogenic and explained the contradiction with IARC by explaining that IARC simply performs a hazard assessment, whereas JMPR carry out a risk assessment. He underlined that Prof. GUYTON (IARC) did not sufficiently stress these differences during her presentation and asked whether she believes that a hazard assessment has the same importance as a risk assessment, as well as further clarification about the differences.

Ms Angeliki LYSIMACHA, Pesticide Action Network Europe (PAN Europe) remarked that there have been cases of people exposed to glyphosate at very low doses which led to the development of Non-Hodgkin lymphoma as presented by Dr GUYTON (IARC) during her presentation. Moreover, she underlined that there have also been genotoxic effects, as well as endocrine disrupting effects of the products containing glyphosate.

Dr TARAZONA (EFSA) confirmed that all potential adverse effects for humans, as well as for the environment, including the ones mentioned by Mr POC, have been covered by the EFSA evaluation. He remarked that EFSA carried out a specific assessment for the endocrine disruptor effects of glyphosate, and this assessment is present in the 6000 pages of the conclusions published by EFSA. Dr Tarazona also recalled that EFSA has specifically indicated in its conclusion that some adverse effects may be triggered by endocrine disrupting mechanisms, and that is an issue that has to be clarified. He also remarked that EFSA has a clear indication that endocrine disruptors effects appear at high doses.

With regard to the formulated products, Dr TARAZONA asserted that while the risk assessment of the products is carried out by the Member States, EFSA recommend including the assessment of the genotoxicity of the products in the evaluation. Finally, he stressed that EFSA is improving the transparency of the process by publishing, in accordance with the EU Regulations, the summary dossier, which is about 4000 pages, and the EFSA assessment, which is about 6000 pages. He also recalled the full report, which is close to 1 million pages, has not been published, as this was not requested by the EU Regulations. Nevertheless, he believes that there is sufficient information and scientific evidence available in both the summary and in the assessment that the transparency is safeguarded.

Dr GUYTON (IARC) replied to the question raised by Prof. ZARUK stating that IARC has tried to be clear in clarifying that they only do the hazard assessment. Moreover, she stressed that on the IARC website they have question and answers that try to clarify the issue which, she believes, is very complicated for many people to understand. In particular, she pointed out that from the hazard evaluation the population can have different impacts depending on the scenarios. She firstly gave the example of the diverse substances that are included in the group 2A ("probably carcinogenic"). Secondly, she mentioned the studies which demonstrated that nurses who work during the night have a higher risk of breast cancer. This evidence explains that based on the hazard evaluation, people can have an increased risk of developing cancer.

She then recalled that the IARC carried out a hazard evaluation and that they have strong evidence from the human studies about the carcinogenicity of glyphosate. She also reiterated that the risk assessment is usually a quantitative estimate of risks associated with a particular exposure and that can differ depending on routes of exposure, intensity, timing and other factors that have to be taken into account. She then emphasised that IARC does not deal with these issues, as they deal with hazard which means evidence that cause cancer under some circumstances. Moreover, she stressed that putting these

circumstances in a specific context is the job of the risk assessors. She concluded by stating that IARC does not make policy recommendations with regard to glyphosate as they only describe the hazard evaluation.

Mr POC expressed his disappointment regarding the answer given by Mr Tarazona (EFSA) and repeated that the metabolic influences as well as the antibiotic property of glyphosate were not taken into account by EFSA. He then questioned the JMPR's recent evaluation on glyphosate by expressing his doubts about the independence of the JMPR's chair.

Mr TARAZONA reiterated that the EFSA evaluation covered all the relevant information available at that time of the assessment, as well as all the potential adverse effects for humans.

2.4. Part III: Perspectives from civil society and doctors

2.4.1. Agriculture and health risks – French experience

Dr Pierre LEBAILLY, PhD, Epidemiologist, Coordinator of the Programme Agriculture et Cancer (AGRICAN) cohort

Dr LEBAILLY focused in his presentation on the cancer risks in agriculture. He explained that according to the literature, while farmers are subjected to low risks of developing some cancers such as those related with smoking (e.g. lung cancer), they are subjected to higher risks of developing some other forms of cancer, such as prostate cancer, lip cancer, melanoma cancer, and others.

He also stressed that from an epidemiologist perspective the crucial task is to measure the exposure to pesticides, as well as to improve the ways the exposure is measured. He also observed that today we have to deal with mechanisms of cancer that are not well known at the moment, such as the epidemic genetic mechanisms. Therefore, he believes, how pesticides are regulated and how certain mechanisms of cancers are measured should be questioned. Moreover, he declared that in order to understand the level of hazards stemming from pesticides it is important to look at the data from the Regulations and also at the peer-reviews in the literature. In particular, Dr Lebailly asserted that in the epidemiological studies as well as for regulation purposes there is currently no gold standard which allows the assessment of the exposure level stemming from (or to) pesticides, as it is difficult to identify people that are exposed and the level to which they are exposed.

Furthermore, Dr Lebailly added that measuring the level of exposure to pesticides is particularly complex as it also depends on the tasks to which pesticides (and pesticide related equipment) are assigned. For instance, there are very few data that allows the measuring of the level of exposure which stems from: a) the personal use of certain pesticides, such as the (cleaning of) sprayers, insecticides on animals, and herbicides between crops; b) the use of certain pesticides as a re-entry task on certain crops and animals; and c) the use of some equipment that was previously exposed to pesticides, such as driving a tractor that was previously assigned to pesticide related tasks and is after assigned to other tasks, (the so called "secondary exposure").

Dr Lebailly then illustrated the main objectives of the AGRICAN cohort study, which are:

- i) dealing with cancer risks related to agricultural activities;
- ii) improving the exposure assessment of different hazards, including pesticides;

- iii) focusing on the effects of hazards of the less studied population (e.g. women, farm workers, etc.)

He then explained that there are several agricultural exposures, and that the AGRICAN study dealt with pesticides used on crops, on animals, and on barns. Moreover, he stated that the AGRICAN cohort study analysed almost 200,000 farmers in France, half of whom were women. All the farmers which were studied were exposed to different pesticides in different measures depending on the type of crops. For instance, according to the results of the study, on the one hand, 80% of men used pesticides on corn, compared to the 12% of women who used pesticides on the same plant. On the other hand, with regard to grapes, almost 100% women were exposed to the re-entry of pesticides.

As a result of five years of monitoring and with 11,000 cancer cases studied, Dr Lebailly explained that with regard to farmers (including farm owners like the Agricultural Health Study and farm workers unlike AHS) there was no observed decrease risk of cancer in the crops, in contrast to what has been published in the literature. As far as the women were concerned, a decrease in the risk of cancer was also not observed. The decreased risk of cancer was only observed on farm owners, but not among farm workers. Overall, statistically significant increased risks of several cancers were also observed for both farm owners and farm workers for prostate cancer, multiple myeloma and, among women only, skin melanoma.

Further, Dr Lebailly focused on the specific case of prostate cancer. In this regard, he explained that the majority of the studies have taken into account only the crude estimate of the exposure of farmers to pesticides used on fruit growing. As a result, no increased risk of developing prostate cancer for farmers was observed. However, he stressed that if studies had taken into account the long term exposure of pesticides on fruit growing, the result would have been an increased risk of developing prostate cancer among farmers, increasing 2 fold for farmers, and those who harvest the fruits, who have been using pesticides for more than 20 years.

Dr Lebailly used this example to stress the need of having a more sophisticated system of evaluation of exposure that can lead to different results than the simple crude estimate studies. Since in Europe, the number of different crops and different active ingredients used in one growing season and moreover during a whole lifetime is high, farm owners and farm workers do not accurately remember the pesticides they used, the team of AGRICAN (Bordeaux and Caen Universities) has developed a crop exposure matrix PESTIMAT.

2.4.2. Options based on clinical daily practices

Prof Dr Xavier Baur, European Occupational and Environmental Medicines (EOM) Society, Founder and President

Prof BAUR started his presentation with the analysis of the dispute between IARC and EFSA. He underlined that while IARC's evaluation was carried out by 17 indicated independent experts in a transparent and rigorous manner, EFSA's evaluation involved more experts who were anonymous. He also observed that there was no clarification on their affiliation as well as on their potential conflict of interests. Moreover, he brought to the attention of the audience the fact that the EFSA dossier did not report the original studies in detail. Moreover, the study descriptions and the assessment was provided by the Glyphosate Task Force (GTF), a consortium of the agricultural industry; the GTF report was amended and redundant parts were deleted by the RMS/EFSA. In addition, some confidential industry studies were taken into account by EFSA and were not disclosed to the public. Furthermore, with regard to the human carcinogenicity studies, EFSA did not

regard case control studies as reliable without any convincing arguments, and did not consider chromosomal studies. Consequently, the EFSA conclusion differed significantly from the one of IARC.

Prof Baur then focused on the main topic of his presentation, namely his clinical experience in the occupation and environmental departments at the hospitals and universities. He stated that the predominant disorders are skin and respiratory disorders, but also lung cancer and mesothelioma which are nowadays predominantly caused by asbestos. In this regard, Dr Baur stressed that there are many parallels between asbestos and the glyphosate situation.

He gave the example of one of his patients, a former power plant worker, who, three decades later, suffered from mesothelioma due to previous asbestos exposure and eventually died. At this point he illustrated a figure showing that in Germany – and similarly in most other western countries - there are at present almost 1,000 new cases every year of mesothelioma due to asbestos exposure. He also stressed that the key aspect to be taken into account is the long latency between the exposure and the development of such diseases, which takes almost 30/40 years to appear. Having this aspect in mind, he made a parallel between asbestos and glyphosate, stating that currently it is impossible to draw final conclusions on the health risks stemming from the use of glyphosate which, due to the long latency of the substance, may appear many years after the exposure. He also noted that recently the WHO published a report which declares that there were 10 million deaths due to asbestos exposure until a worldwide ban of the substance was put in place. Further, he pointed out that the mesothelioma case is not only an ethical issue, but also an economic issue considering the relevant costs for European countries to diagnose and treat mesothelioma (1,684 million euro annually in 15 countries). It is also an environmental issue as asbestos contamination poses a significant mesothelioma risk on the general society, despite this the industry still trivialise and deny its risks.

With regard to the disorders in farmers and agricultural workers, based on his clinical daily outpatient practice, Dr Baur observed that these sectors developed various types of cancer, such as Non-Hodgkin-Lymphoma (NHL), bladder cancer, but also polyneuropathia and other disorders caused by different pesticides and herbicides.

He then gave the example of a patient who worked between 1953 and 1996 in different farms and heavily used various herbicides and pesticides, including glyphosate. He developed an NHL, a cancer of the lymphatic system. Usually 50% of affected people do not survive after five years. Dr Baur also emphasised how difficult it is to find the cause of the disease, which can be the consequence of glyphosate exposure, but also of pesticide, genetic and unknown origin.

Finally, Dr Baur stated that it is possible to learn a lot from the asbestos story and to translate the findings to the current glyphosate situation. Firstly, if interest groups keep trivialising or even denying the proven health risks stemming from glyphosate exposure, the risk at stake is to have a pandemic, like the asbestos one, which, according to the WHO, is killing 10 million people world-wide. Secondly, glyphosate and its formulations represent a new potentially hazardous internal load to the human body and the health risk is incalculable at present. Thirdly, based on experience with other environmental carcinogens, precaution is strongly recommended: there should be no contamination of everyday food, beverages, the environment, since cumulative long term effects may occur as already demonstrated in the asbestos case. Fourthly, not only after the asbestos pandemic and the diesel affair, it is evident that the current practice of risk assessment of potentially endangering agents does not sufficiently protect the health of European workers and citizens and the environment. He concluded by stating that the MEPs have a high

responsibility for the health of the next generations and they should not pose an incalculable risk on them.

2.4.3. Approaches to management of glyphosate and disease prevention

Ms Génon JENSEN, Health and Environment Alliance (HEAL), Executive Director

Ms JENSEN presented the Health and Environment Alliance (HEAL) which is a membership network composed of 70 organisations in 28 countries, including doctors' associations, patient groups, nurses' associations, public health institutes, environmental groups, and pesticide action networks. HEAL promotes health within environmental policies.

Ms Jensen expressed the concern of HEAL about the reauthorisation of glyphosate, particularly because of the new science on its carcinogenic and potential endocrine disrupting properties. The first concern is summarised in the Scientists' Consensus Statement published in February 2016 in the Journal of Environmental Health²⁰ which outlines the increased human exposure on glyphosate and the adverse health outcomes that the exposure can cause. Glyphosate use has increased considerably over the last 30 years, such that human exposure has also vastly increased, which should be a reason for caution in decision making, particularly if there are scientific indications of potential harm.

Exposure of all Europeans is likely – recent findings showed glyphosate in the urine of 99% of Germans tested (2000 people), and more recently 100% in the MEPs who volunteered for urine analysis. In particular, the growing and relatively new use of glyphosate shortly before harvest for desiccation of plants is an important new contributor to the increase in residue frequency and levels in some grain-based food products. The second concern of HEAL is about the long term persistence of glyphosate in the environment. The third concern is the carcinogenic effects of glyphosate. In this respect, Ms Jensen pointed out that pursuant to the EU law if pesticides are carcinogens (Category 1B) they cannot be authorised, therefore HEAL believes that, on the basis of the hazard assessment by IARC on carcinogenicity, and the scientific indications of endocrine disruption in mind, glyphosate should not be authorised at EU level. The fourth HEAL's concern is about the glyphosate effects on nutrient balance.

The fifth concern, Ms Jensen explained, is about the possible endocrine disruptor properties of glyphosate as scientific evidence links its exposure to endocrine disrupting chemicals. It is not about the assessment of risk, it is about whether the active substance has the inherent property of causing endocrine disruption which means it can interfere with natural hormones, the chemical messengers of our bodies and biological functions. The latter are a cause of concern since EDCs are not only implicated in severe diseases such as breast, prostate and testicular cancer, they may cause fertility problems, diabetes, obesity, as well as learning and behavioural problems in children. If glyphosate is an endocrine disruptor, the pesticides' law forbids it from being authorised.

Ms Jensen made several points on the differences between IARC, which does hazard assessment, whereas EFSA does risk assessments. IARC is the gold standard in *hazard assessments*; they rely solely on data available in the public realm. According to EU practice, to declare a substance carcinogenic what is needed is 'sufficient' evidence, *as a minimum*, in two animal species or in two separately conducted animal studies, which IARC found. Despite this, EFSA/Bfr analysis have dismissed these studies which provoked a response from 94 scientists who have written an open letter to Commissioner Andriukaitis

²⁰ John Peterson Myers et al., Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement, Environmental Health 2016;15:19, February 2016, available at: <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0> (accessed June 2016).

stressing that the EFSA's conclusion on glyphosate is "*scientifically unacceptable*", "*fundamentally flawed*", and "*misleading*". In February 2016, a scientific consensus stated that "*the current level of exposures to glyphosate-based herbicides can induce adverse health outcomes*" and that "*the current EU ADI is probably at least three fold too high, based on a transparent, fully documented review of the [same] data*" (same as the German Federal Institute for Risk Assessment).

Ms Jensen then went on to put the decision making on glyphosate in the context of managing and preventing disease. An under recognised and under resourced area is *primary* prevention, which is making sure that environmental contaminants that can cause disease are reduced or prevented. HEAL strongly believes more needs to be done on primary prevention to reduce exposure to glyphosate, including as a minimum for glyphosate i) address outdated TDIs; ii) strict limits on pre-harvest use; iii) stop use by non-professionals; and iv) stop use in or near public parks, playgrounds.

HEAL is one of several health actors working on primary prevention of glyphosate. The European Cancer Leagues (ECL), bringing together national charities across the EU, co-hosted with MEPs against Cancer a briefing on glyphosate stating the "*IARC's findings suggest that banning glyphosate should be part of Europe's cancer prevention policy*". Different cancer societies and medical groups in Portugal, France, Belgium, the UK and Malta are calling for greater health protection by reducing or eliminating glyphosate use. For example, le Ligue contre le cancer in France, with a membership of 700,000, has launched a petition against renewal of the licence for glyphosate by the European Union authorities. It recently welcomed the French government's stance against the renewal of glyphosate's authorisation:

In conclusion, she stressed that along with a growing number of health groups such as cancer charities or medical associations, HEAL believes that the re-approval of glyphosate is against EU law and against the public will, as two-thirds of the public does not want glyphosate used and this number is increasing. Moreover, glyphosate may pose probable long term public health consequences and if glyphosate will be re-approved it is likely that more non Hodgkin Lymphoma cases, a tumour with a 50% mortality rate, will be seen in the population. Lastly, she also emphasised that individuals cannot choose to avoid glyphosate exposure, unlike some lifestyle choices. For all these reasons HEAL strongly believes that the EU should not re-authorise glyphosate.

2.4.4. Closing remarks by the Chair

In his closing remarks, Mr PETERLE stated that there is a problem as the European political decision makers are divided on the issue of glyphosate. He also expressed his contentment about the recent position of the European Parliament which he hoped will be respected by the European Commission. Moreover, he wished that a proactive approach will be developed with regard to the development and identification of safe alternatives to glyphosate, and urged for the application of the precautionary principle as explained by Dr Douma in his presentation. Mr Peterle also underlined that it will be important to take a decision on this issue, stressing that even a non-decision would be a decision. Finally, he stated that if mitigation measures have to be used, he thinks that these measures will be harmful to human beings.

ANNEX 1: PROGRAMME

WORKSHOP

EU's Pesticide Risk Assessment System: The Case of Glyphosate

24 May 2016 from 12.30 to 14.45

European Parliament, Paul-Henri Spaak 4B001, Brussels

**Organised by the Policy Department A-Economy & Science
for the Committee on the Environment, Public Health and Food Safety (ENVI)**

AGENDA

12.30 - 12.40

Opening and welcome

MEP Mr Alojz PETERLE, co-Chair ENVI Health Working Group

Part 1:

EU policy context and latest developments

12:40 -12:50

Glyphosate: the process and latest EU policy developments

Ms Sabine JUELICHER, European Commission, DG SANTE, Director for Food and feed safety, innovation

12:50 – 13:00

Regulating environmental risks: the case of glyphosate

Dr Silvia Pieper, German Environmental Agency (UBA), Senior Scientific Officer - Ecotoxicology

13:00 – 13:10

Status of precautionary principle in EU risk management

Dr Wybe DOUMA, T.M.C. Asser Institute, Senior Researcher

13:10 – 13:20

Questions & Answers

Part 2:

Challenges and options based on available research and evidence

13:20 – 13:30

Glyphosate - from the identification of hazards to the evaluation of risks

Mr Jose Vicente TARAZONA, European Food Safety Authority (EFSA), Head of Unit (Pesticides)

13:30 – 13:40

The carcinogenicity of glyphosate

Dr Kate GUYTON, World Health Organisation (WHO), International Agency for Research on Cancer (IARC), Senior Toxicologist at the IARC Monographs Programme

13:40 – 13:50

ECHA's Evaluation of glyphosate

Dr Jack DE BRUIJN, European Chemicals Agency (ECHA), Director of Risk Management

13:50 – 14:00

Questions & Answers

Part 3:

Perspectives from civil society and doctors

14:00 – 14:10

Agriculture and health risks - French experience

Mr Pierre LEBAILLY, Coordinator of the Programme Agriculture et Cancer (AGRICAN) cohort

14:10 – 14:20

Options based on clinical daily practice

Prof. Dr Xaver BAUR, European Occupational and Environmental Medicines (EOM) Society, Founder and President

14:20 – 14:30

Approaches to management of glyphosate and disease prevention

Ms Génon JENSEN, Health and Environment Alliance (HEAL), Executive Director

14:30 – 14:40

Questions & Answers

14:40 – 14:45

Closing remarks by the Chair

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Ms Sabine JÜLICHER

Ms Jülicher holds a veterinary degree from the Free University Berlin and has a postgraduate qualification in food hygiene. She initially worked in research, later in public administration on a national and international level. Ms Jülicher joined the European Commission in 1999, working in the area of food safety before taking up management functions. She has been the Director of the Directorate for Food and feed safety, innovation since 1 January 2016.

Dr Silvia PIEPER

Dr Pieper currently focuses on the ecotoxicology and environmental risk assessment of Plant Protection Products (PPP), both in the active substance assessment for EU approval as well as in the authorisation procedure for PPP at zonal, national level. She is involved in the preparatory work and the development of several guidance documents (EFSA working groups; SANTE guidance) and since last year she has been a member of the EFSA Panel on Plant Protection Products and their Residues (PPR). Her scientific background is the ecology and ecotoxicology of soil fauna, with particular interest in its functional role and the provision of ecosystem services by soil organisms. Her expertise covers especially higher tier risk assessment in terrestrial environments, pesticide effects on terrestrial biodiversity (arthropods, soil organisms, amphibians & reptiles) and the impact of climate change on pesticide use and effects.

Dr Wybe DOUMA

Dr Douma studied law at the University of Groningen (the Netherlands) and the Eberhard Karls University, Tübingen (Germany) and wrote his PhD on the application in international, European and Dutch Law of the precautionary principle. He is senior research fellow at the T.M.C. Asser Institute for International and European and lecturer of International Environmental Law at The Hague University. His working experience includes lecturing and advising on European and international environmental law and issues of sustainable development in the EU and its neighbouring countries, South America and Asia to students, civil servants, judges, public prosecutors and diplomats. He worked in a wide range of EU environmental approximation projects, and senior legal expert in a team advising the European Commission on methods to apply the precautionary principle in EU chemicals' law. Dr Douma was seconded to the Legal Department of the Dutch Environment Ministry over an extensive period. He is co-founder and editor-in-chief of the European environmental law website (www.eel.nl), editor of several environmental law journals and frequently publishes on a variety of Dutch, European and international environmental law issues. He is a board member of the Centre for the EU Law on External Relations (CLEER), member of the editorial board of the Proceedings of the Estonian Academy of Security Sciences and on the board of referees of the Lisbon Law Review. Currently he is working on finalising a report on the TTIP and the precautionary principle.

Mr Jose Vicente TARAZONA

Dr Tarazona, is a Doctor in Veterinary Medicine with a PhD in Toxicology. He developed his professional career as Assistant Professor of Toxicology at the University of Madrid and then as researcher and Head of Department at the Spanish National Institute for Agriculture and Food Research, serving also as a member of several EU, OECD and UN

scientific committees. In 2009, he moved to the European Chemicals Agency (ECHA) as Chair of the Committee for Risk Assessment and Scientific Chair for Evaluation. Dr Tarazona has been head of the Pesticides Unit at the European Food Safety Agency (EFSA) since 2013.

Dr Kate GUYTON

Dr Kate Guyton is a Senior Toxicologist at the International Agency for Research on Cancer (IARC), World Health Organization in Lyon, France. Dr Guyton received her scientific training in the United States. She earned her BA (cum laude) and her PhD degrees from Johns Hopkins University, and postdoctoral training at the National Institutes of Health. Dr Guyton has been certified as a Diplomat of the American Board of Toxicology since 1998. Prior to joining IARC, she worked for the United States Environmental Protection Agency (2005-2014), receiving a Gold Medal for exceptional service. She also has experience, as the Director of Scientific Affairs at CCS Associates (1998-2005), working with the United States National Cancer Institute. Dr Guyton has authored more than 50 scientific publications in her area of expertise.

Dr Jack DE BRUIJN

Jack de Bruijn started working at the European Chemicals Agency (ECHA) from the start in September 2007. He is currently heading the Risk Management Directorate that is responsible for identifying and implementing the authorisation and restrictions' processes under REACH as well as managing the classification related tasks resulting from the CLP Regulation. Since the beginning of 2014 the Directorate also manages and coordinates ECHA's scientific evaluations and assessments under the Biocidal Products Regulations (BPR).

Before joining the Agency, he worked at the European Chemicals Bureau (ECB) of the JRC in Ispra where he coordinated the development of the guidance documents for REACH. Before joining the ECB he worked for many years for the Dutch national authorities in the area of regulatory risk assessment of chemicals. He is a chemist by training and has a PhD in environmental toxicology.

Dr Pierre LEBAILLY

Pierre LEBAILLY, born in 1969, with an initial education background in biochemistry and toxicology followed by a PhD in Epidemiology on pesticides and cancer with a special attention on use of biomarkers of genotoxicity used among farmers. He spent more than one year at a post-doc in the Molecular Epidemiology Unit of Leeds University working on genetic susceptibility of AML cases. He is now a lecturer in Public Health and Epidemiology at the Caen Normandy University in France since 2006 and researcher and Deputy Head of the INSERM Unit Cancers & Preventions at the Comprehensive Cancer Center François Baclesse since 2012. He is one of the Principal Investigators and the coordinator of the AGRiculture & CANcer (AGRICAN) cohort, he is a member of the steering committee of the international consortium of agricultural cohorts (AGRICOH) coordinated by IARC and NCI since 2010. He has published more than 50 papers in English peer-reviewed journals mainly in epidemiology, occupational health and molecular epidemiology.

Prof. Dr Xavier BAUR

Professor Baur received primary education and training in farming, and secondary in medicine. He graduated at the LMU University Munich where he obtained his Internship, finished Residency and became Dr.Sci. at the LMU University Munich. He obtained Board Certifications: Internal Medicine, Cardiology, Pulmonary Medicine, Occupational Medicine, Allergology, Environmental Medicine. He chaired Occupational Medicine at the University of Hamburg and Bochum, and was director of the two Institutes for Occupational Medicine at the Universities of Hamburg and Bochum from 1990 until September, 2012. After his retirement at the end of 2012, he was awarded a senior professorship at the Haukeland University Hospital, Bergen, Norway, and has been a Visiting Scientist at the Charité University of Medicine, Berlin, Germany. His current work focuses on diagnostics, health of miners, asbestos and agricultural workers. Xavier Baur is the initiator and current president of the charity European Occupational and Environmental Medicine (EOM) Society. He is also (advisory) board member of several scientific journals, e.g. of The Lancet Respiratory Medicine. Since 2012 he is Collegium Ramazzini Fellow. He has been chair, co-chair, and member of several European and national task forces, i.e. of the European Respiratory Society and several German medical scientific societies developing diagnostic guidelines and position papers on diagnostics, management, prevention and compensation of work-related respiratory disorders, new lung function reference values, and ethical issues related to occupational and environmental medicine.

Ms Génon JENSEN

Génon K. Jensen is the Founder and Executive Director of the Health and Environment Alliance (HEAL). Ms Jensen has been an official member of the World Health Organization's European Environment and Health process, representing the health sector since 2000, and serves on the WHO European Region's Health in Climate Change committee. She is also on the Steering Committee of the International POPs Elimination Network, and serves as the coordinator for the working groups on climate and asthma of the US Collaborative on Health and the Environment (CHE), and co-chairs the EDC Strategy Group which highlights new science, EDC Science Briefs through a teleconference series. She received the 2014 Clean Air in Cities Award for her valuable personal contribution to improving air quality in London and elsewhere.

Genon K. Jensen is a co-author of several publications and reports, including "Halting the child brain drain: why we need to tackle global mercury contamination" (2006), "Acting NOW for better health: A 30% reduction target for EU climate policy" (2010), "The Unpaid Health Bill: How coal power plants make us sick" (2013), and "Health costs in the EU - How much is related to EDCs?" (2014). She also publishes in journals: "Early-life prevention of non-communicable diseases", The Lancet, Volume 381, Issue 9860, Pages 3 - 4, 5, January 4, 2013; and "Revising the EU Strategy on endocrine disruptors: nearing a decisive moment", Journal of Epidemiology & Community Health, 10.1136/jech - 2012 - 201747, November 9, 2012. Ms Jensen has a degree in journalism and international politics from George Washington University in Washington, DC and an MA in European Administrative Studies from the College of Europe, Belgium.

ANNEX 3: PRESENTATIONS

Presentation by Ms Sabine Jülicher



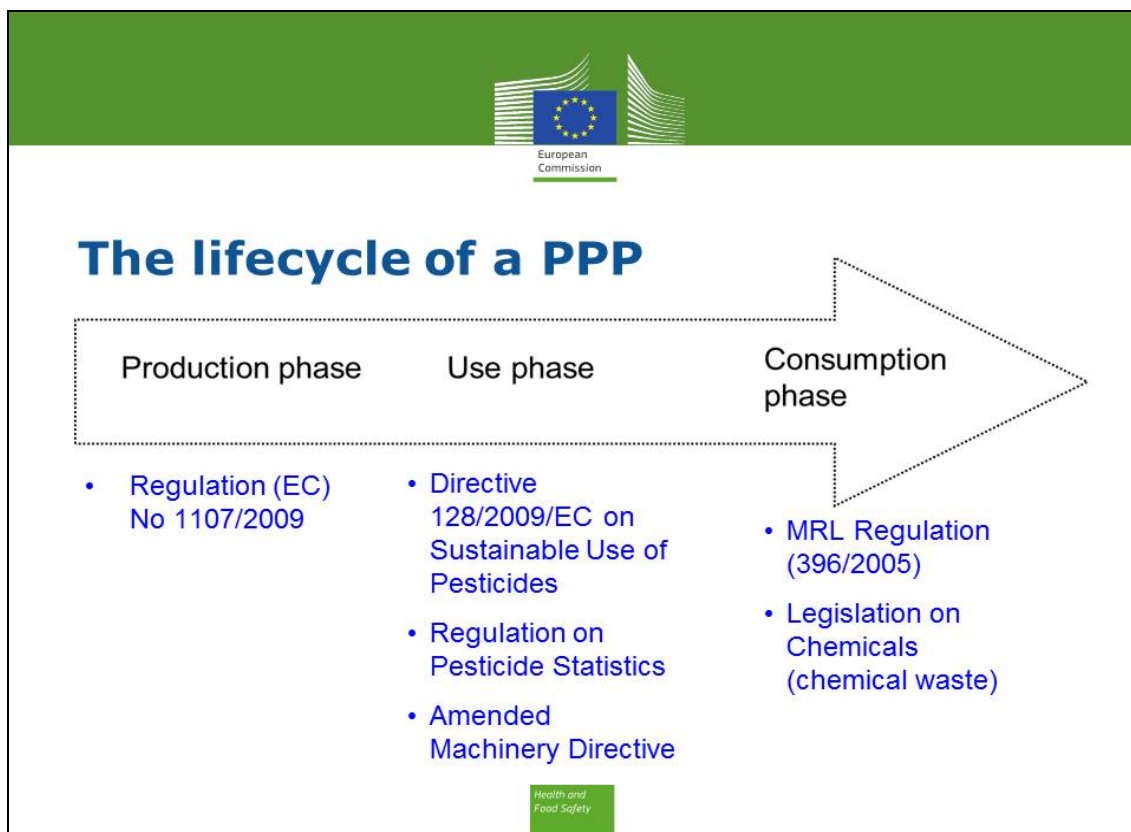
European Parliament workshop: 'EU's pesticide risk assessment system: the case of glyphosate'

Glyphosate: the process and latest EU policy developments

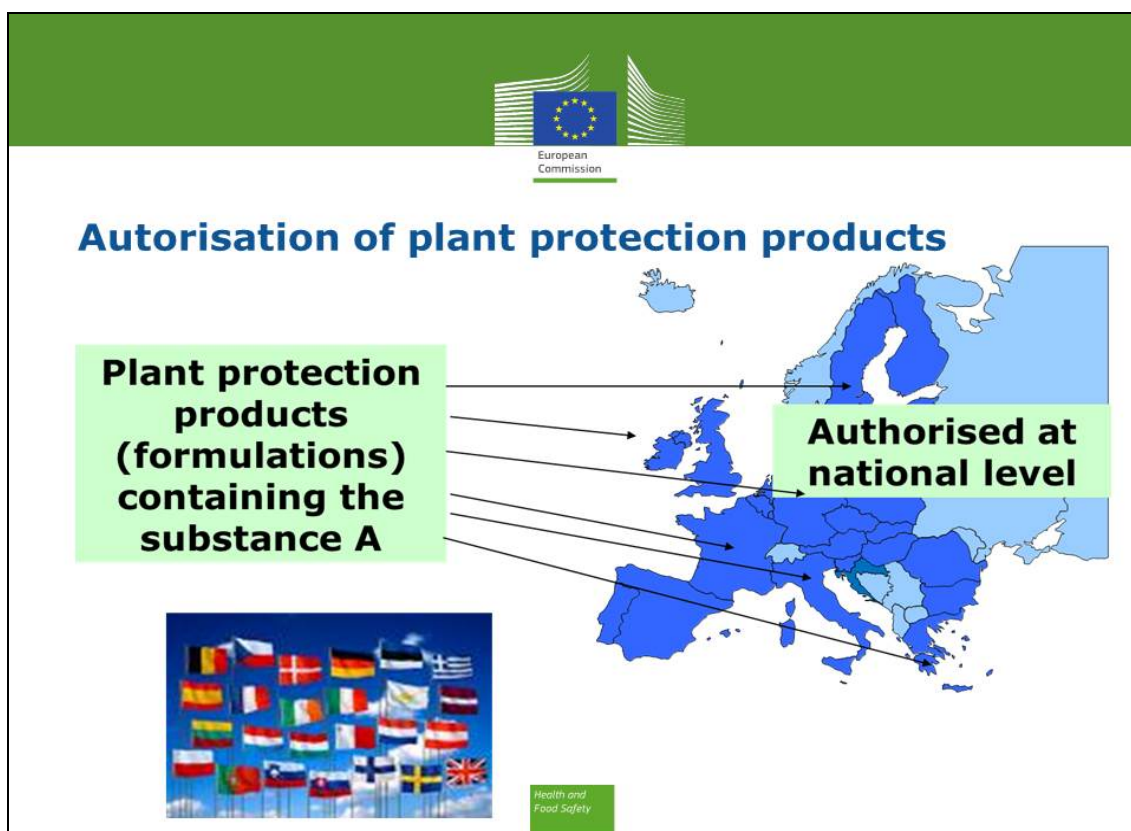
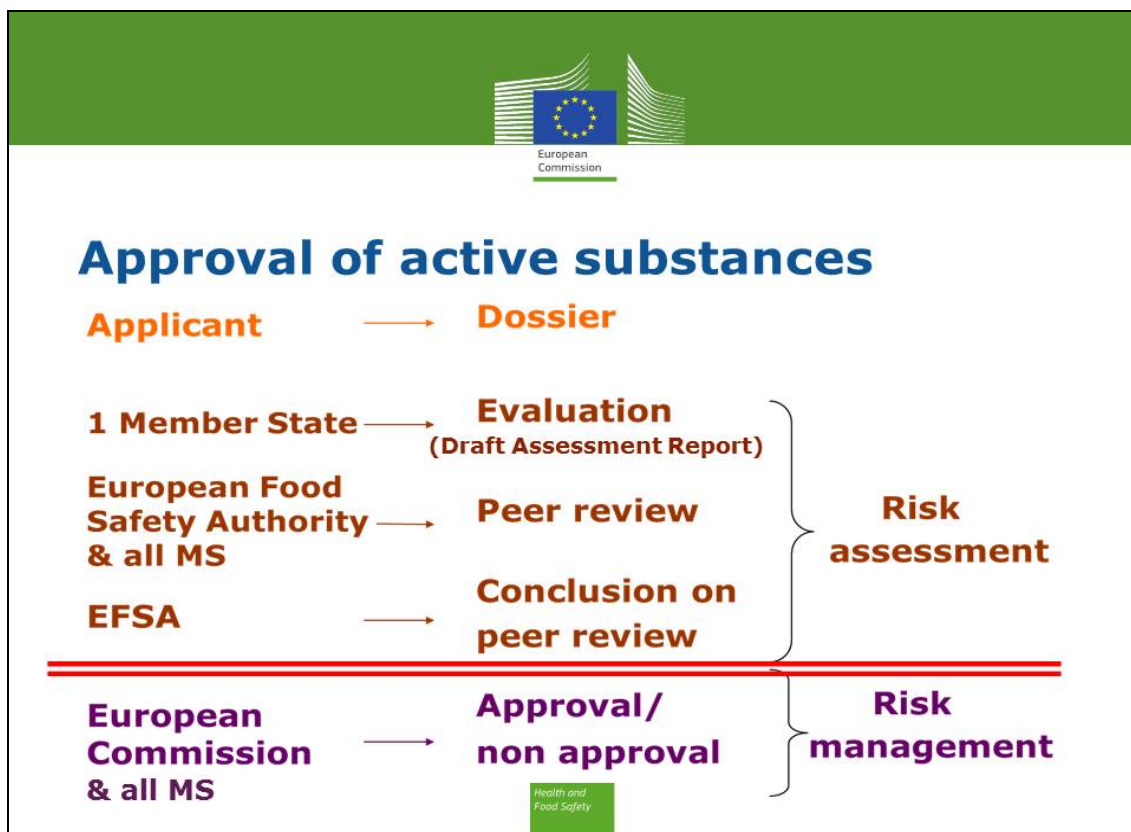
Tuesday 24 May 2016

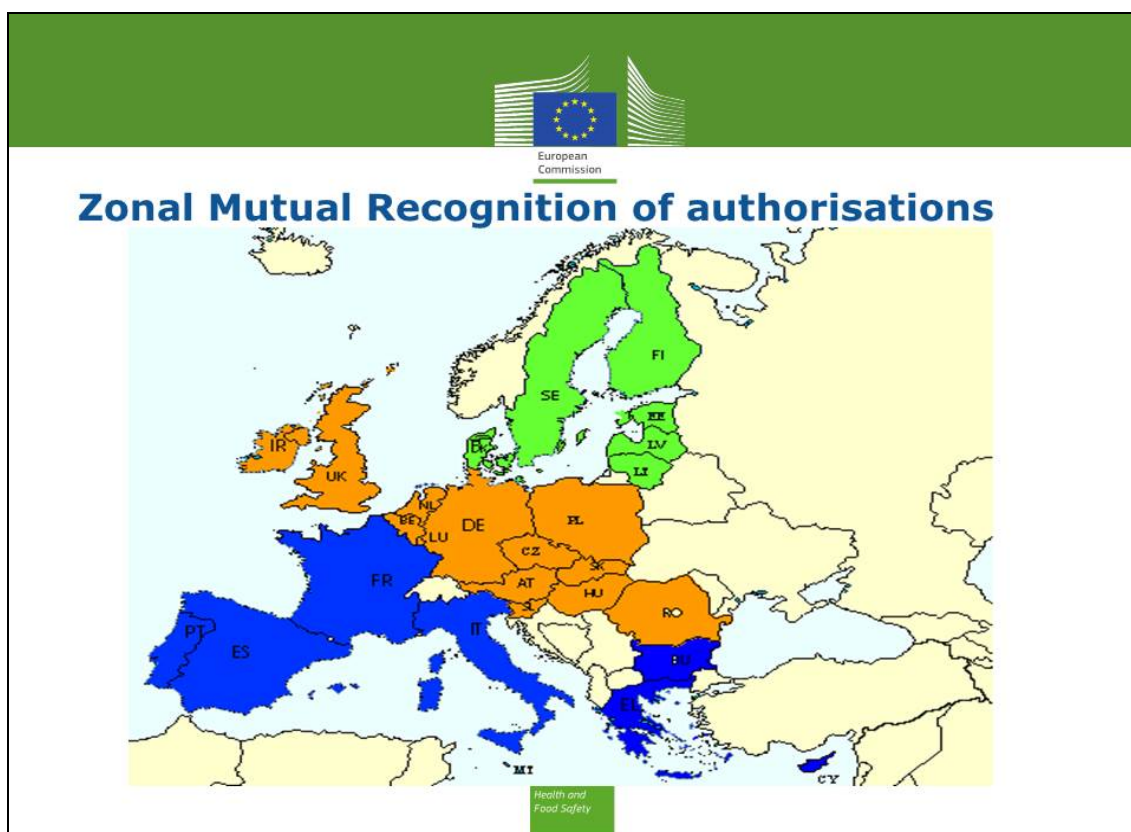
Sabine Jülicher
Director

European Commission
DG Health and Food Safety
Directorate E – Food and feed safety, innovation









Thank you very much for your attention!

http://ec.europa.eu/food/plant/pesticides/index_en.htm

Presentation by Dr Silvia Pieper

Für Mensch & Umwelt

**Umwelt
Bundesamt**

EU's pesticide risk assessment system: the case of glyphosate

Regulating environmental risks: the case of glyphosate

Silvia Pieper, Tobias Frische, Jörn Wogram

Environmental Risk Assessment of Plant Protection Products
Federal Environment Agency (Umweltbundesamt, UBA)

Regulating environmental risks of glyphosate

WHY IS GLYPHOSATE AN ENVIRONMENTAL CASE?

- **BROADSPECTRUM HERBICIDE**
 - NON-SELECTIVE IN EFFECTS AND SIDE-EFFECTS
- **BROADSPECTRUM USE**
 - INTENDED USES ARE 'ALL CROPS' (PRE- AND POST-PLANTING), FORESTS, GRASSLAND, NON-ARABLE LAND, PARCS, PRIVATE GARDENS...
- **HIGH RISKS FOR THE ENVIRONMENT**
 - PLANTS, TERRESTRIAL VERTEBRATES
 - DISRUPTION OF FOOD WEBS

24.05.2016 | the case of glyphosate 2

Regulating environmental risks of glyphosate

HOW TO DECIDE UNDER CURRENT LEGISLATION?


- **ACTIVE SUBSTANCES SHALL BE APPROVED ONLY IF [i.a.] THERE ARE NO UNACCEPTABLE EFFECTS ON THE ENVIRONMENT**
 - ON NON-TARGET SPECIES
 - ON BIODIVERSITY AND THE ECOSYSTEM
- **CAN RISK ASSESSMENT ALONE TELL THE GOOD FROM THE BAD?**
 - ORGANISMS AKIN TO THE TARGET ARE AT RISK
 - NO EFFECT WITHOUT SIDE-EFFECT
 - RISK ASSESSMENT CONCLUDES ON HIGH RISK AREAS
- **APPROVAL IS SUBJECTED TO CONDITION AND RESTRICTIONS**
 - RISK CONTROLLABLE ONLY BY MEANS OF RISK MITIGATION MEASURES

24.05.2016 | the case of glyphosate

3

Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

RISK ASSESSMENT		
Areas at risk	NON-TARGET PLANTS	
effects	direct toxic effects	
RISK MANAGEMENT		
mitigation measures		

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Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

RISK ASSESSMENT

Areas at risk NON-TARGET PLANTS

effects direct toxic effects



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RISK MANAGEMENT

mitigation measures drift reduction and/or in-field no-spray buffer zones for all representative uses



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Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

RISK ASSESSMENT

Areas at risk DIVERSITY OF ARTHROPODS AND VERTEBRATES

effects Indirect effects via trophic interactions

RISK MANAGEMENT

mitigation measures

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6

Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

RISK ASSESSMENT

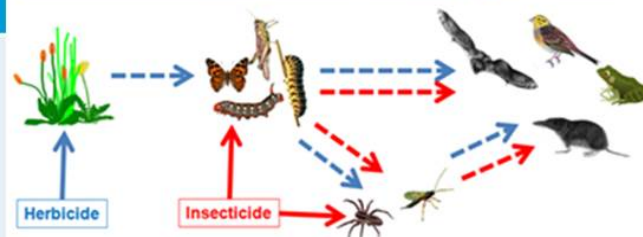
Areas at risk DIVERSITY OF ARTHROPODS AND VERTEBRATES

effects Indirect effects via trophic interactions



RISK MANAGEMENT

mitigation measures



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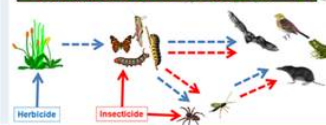
Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

RISK ASSESSMENT

Areas at risk DIVERSITY OF ARTHROPODS AND VERTEBRATES

effects Indirect effects via trophic interactions



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RISK MANAGEMENT

mitigation measures ecological compensation areas (unsprayed, non-crop conservation headlands, beetle banks, flowering strips...)



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Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

- WHY ARE ECOLOGICAL COMPENSATION AREAS NECESSARY IN THE RISK REGULATION OF GLYPHOSATE?



Typical agricultural areas in Lower Saxony (left) and Saxony-Anhalt (right). Both areas: 4 hectare © GoogleMaps 2009

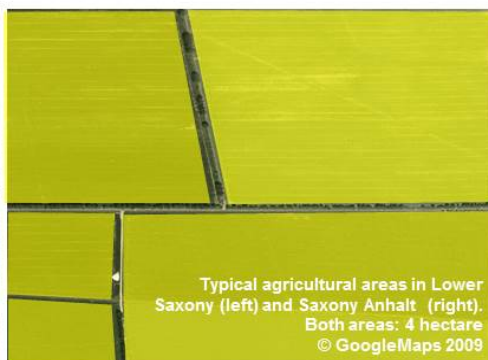
24.05.2016 | the case of glyphosate

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Regulating environmental risks of glyphosate

RISK REGULATION OF GLYPHOSATE

- WHY ARE ECOLOGICAL COMPENSATION AREAS NECESSARY IN THE RISK REGULATION OF GLYPHOSATE?



Typical agricultural areas in Lower Saxony (left) and Saxony-Anhalt (right). Both areas: 4 hectare © GoogleMaps 2009

→ BIODIVERSITY PROTECTION NEEDS A MINIMUM SHARE OF UNSPRAYED, NON-CROP AREAS TO OFFSET FOOD WEB DISRUPTION

24.05.2016 | the case of glyphosate

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Regulating environmental risks of glyphosate

EMERGED RISKS – IMPROVED RISK MITIGATION

■ RESEARCH PROVIDES

→ *SCIENTIFIC EVIDENCE* OF FOOD WEB DISRUPTION
BY GLYPHOSATE AND OTHER BROADSPECTRUM HERBICIDES

■ AGRI-ENVIRONMENTAL MEASURES PROVIDE

→ *PRACTICAL EVIDENCE* ON THE EFFECTIVENESS OF ECOLOGICAL
COMPENSATION AREAS IN OFFSETTING PPP EFFECTS

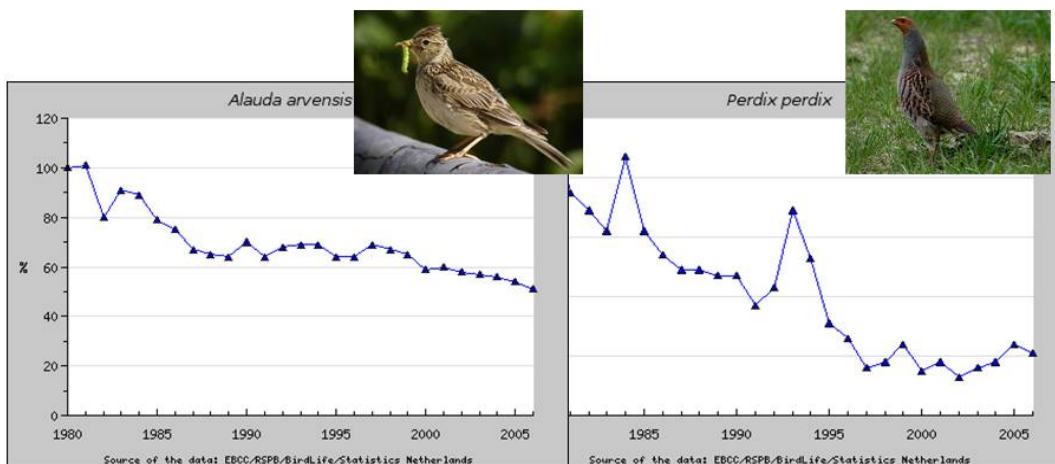
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Regulating environmental risks of glyphosate

EMERGED RISKS – IMPROVED RISK MITIGATION

■ TYPICAL SPECIES IN AGRICULTURAL AREAS: DOWNWARD TRENDS



→ FOOD SHORTAGE ALSO DUE TO PESTICIDE USE

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Regulating environmental risks of glyphosate

EMERGED RISKS – IMPROVED RISK MITIGATION

▪ EXAMPLE OF SUCCESSFUL MITIGATION OF INDIRECT EFFECTS ON TERRESTRIAL FOOD WEB



Flowering field margin in a grey partridge conservation project (Göttingen, DE)
(<http://www.rebhuhnenschutzprojekt.de>)

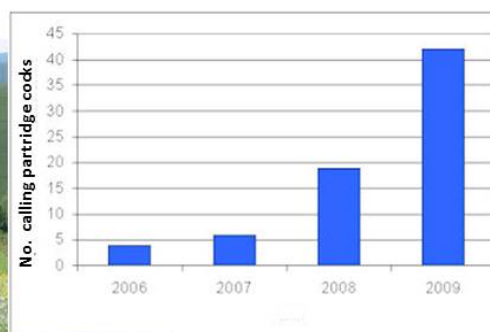
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Regulating environmental risks of glyphosate

EMERGED RISKS – IMPROVED RISK MITIGATION

▪ EXAMPLE OF SUCCESSFUL MITIGATION OF INDIRECT EFFECTS ON TERRESTRIAL FOOD WEBS



Flowering field margin in a grey partridge conservation project (Göttingen, DE)
(<http://www.rebhuhnenschutzprojekt.de>)

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Regulating environmental risks of glyphosate

EMERGED RISKS – IMPROVED RISK MITIGATION

▪ THE SETTING-UP OF ECOLOGICAL COMPENSATION AREAS

→ SHOULD NOT BE COMPULSORY

▪ THE EXISTENCE OF ECOLOGICAL COMPENSATION AREAS

→ SHOULD BE A PRECONDITION FOR THE USE OF GLYPHOSATE-BASED PLANT PROTECTION PRODUCTS (PPP)

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Regulating environmental risks of glyphosate

EMERGED RISKS – IMPROVED RISK MITIGATION

▪ RISK MITIGATION AREAS AS PRECONDITION FOR THE USE OF PPPS

→ ARE ALREADY IN PLACE AND ARE DEEMED REASONABLE
(E.G. VEGETATED BUFFER STRIPS FOR RUN-OFF MITIGATION)



© Rainer Oppermann, UBA-Texte 30/2014

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Regulating environmental risks of glyphosate

SUCCESSFUL RISK REGULATION OF GLYPHOSATE

▪ **RISK ASSESSMENT OF GLYPHOSATE HAS IDENTIFIED INDIRECT EFFECTS ON FOOD WEBS AS AN EMINENT THREAT TO TERRESTRIAL BIODIVERSITY.**

- BIODIVERSITY IN AGRICULTURAL LANDSCAPE IS FUNDAMENTAL FOR THE DELIVERY OF CRITICAL ECOSYSTEM SERVICES.
- MANAGEMENT MEASURES NEED TO TAKE IMPROVED RISK MITIGATION MEASURES INTO ACCOUNT.
- ECOLOGICAL COMPENSATION AREAS ARE EFFECTIVE AND REASONABLE IN THE IMPLEMENTATION.

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Regulating environmental risks of glyphosate

SUCCESSFUL RISK REGULATION OF GLYPHOSATE

IS POSSIBLE


IS REASONABLE

IS ESSENTIAL

**THERE IS NO REASON
FOR NOT GETTING STARTED RIGHT AWAY**

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**Umwelt
Bundesamt**


Thank you for your attention


Silvia Pieper, Tobias Frische, Jörn Wogram
silvia.pieper@uba.de

www.uba.de/en/topics/chemicals/plant-protection-products
www.uba.de/en/publikationen/protection-of-biodiversity-of-free-living-birds
www.uba.de/en/press/pressinformation/plant-protection-less-is-best-lower-risk

Presentation by Dr Wybe Douma

ASSER
INSTITUTE *Centre for International & European Law*






Status of the Precautionary Principle in EU Risk Management

Dr. Wybe Th. Douma
w.t.douma@asser.nl

Workshop "EU's pesticide risk
assessment system: the case of
glyphosate", European Parliament
24 May 2016

1

ASSER INSTITUTE



Content

- 1) **Origins of Precautionary Principle (PP)**
- 2) **Codification of PP in European Union Law**
- 3) **Commission Communication 2000(1) on the PP**
- 4) **PP in CJEU Jurisprudence**
- 5) **Concluding remarks**

2



1) Origins of the Precautionary Principle

German environmental law, 'Vorsorgeprinzip'

North Sea conferences

Principle 15 Rio Declaration (UNCED, 1992):

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Codification in numerous IEL treaties

3



2) Codification of PP in European Union law

- 1987 environmental title without PP
- 1993 PP inserted in environmental title
- nowadays Article 191 TFEU:

Union policy on the environment shall aim at a high level of protection [and] **shall be based on the PP** and on the principles that **preventive action** should be taken [+ rectification at source & polluter pays]

- no definition offered
- status of this principle?
- references to PP in secondary law

4



3) Commission Communication 2000(1) on PP

No definition of PP. Instead:

- **explanations + guidelines** on **when & how to use it**
- PP not only for environmental issues but all potential risks to **environment, human, animal or plant health**
- No threshold 'serious' and/or 'irreversible' damage
- Distinction: prudent approach in risk assessment phase & applying PP in risk management phase
- **Reversal burden of proof** in individual cases where substance like pesticide is *a priori* (potentially) hazardous
- Risk management decision can be: no measures for time being, or precautionary measures (warning, ban, etc)

5



4) PP in CJEU jurisprudence

- Confirmation that PP **must** be used for potential risks to **environment, humans, animals, plants**
- Setting out **circumstances** in which PP can be used
- Explaining how PP provides legislator **discretion** to adopt measures
- **Forcing** EU legislator to **adopt** precautionary measures?

6



Two recent CJEU case law examples:

Neptune Distribution, C-157/14 of 17 Dec. 2015:

“EU legislature must take account of the precautionary principle, according to which, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent”

‘Pillbox 38’, Case C-477/18 of 4 May 2016:

“the identified and potential risks linked to the use of electronic cigarettes [...] required the EU legislature to act in a manner consistent with the requirements stemming from the precautionary principle.”

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5) Concluding remarks

In line with TFEU, CJEU case law & Commission guidelines on application of PP:

- EU institutions **obliged** to apply PP in cases where there is **uncertainty** as to **existence** or **extent** of **risks** -> **BINDING NORM**
- PP **justifies** adoption of **restrictions** where **likelihood of real harm persists** should risk materialise.
- Decision not to adopt restrictions is to be **motivated**, identifying what is known & gaps in knowledge, and setting out in detail why potential risks did not warrant adoption of restrictions.

Further information:

N. van der Bergh, M. Blainey, W.Th. Douma, G. Goldenman and I. Pratt, '[Considerations on the application of the Precautionary Principle in the EU chemicals sector](#)', report for Eur. Commission, July 2011

European Environmental Law

website www.eel.nl

EEL News Service

@EurEnvLaw Twitter

W.T.Douma@asser.nl

Presentation by Dr José Tarazona




Glyphosate: from the identification of hazards to the evaluation of risks


Dr José V. Tarazona
Head Pesticides Unit

European Parliament, 24 May. 2016

 **efsa**
European Food Safety Authority


www.efsa.europa.eu




 **efsa**
European Food Safety Authority

PUBLIC HEALTH ASSESSMENT FOR PESTICIDES

- 1. Hazard identification**
(EU - EFSA & ECHA; WHO - IARC & JMPR)
 - CLP/UN-GHS Classification & Labelling
 - IARC Grouping
- 2. Hazard characterisation & potency (EFSA - JMPR)**
 - Mode of action and toxic effects
 - Critical effects for risk assessment: Toxicological Reference Values
- 3. Exposure assessment (EFSA - JMPR)**
 - Residue levels in food
 - Food consumption (EU diets)
- 4. Risk for consumers (EFSA - JMPR)**



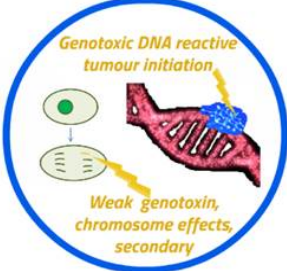
2



1. HAZARD IDENTIFICATION: TUMOUR DEVELOPMENT

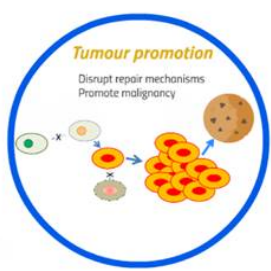
1. Assessment of available evidence in humans and animals
2. Assessment of tumour induction mechanisms and relevance for humans

Initiation -- Promotion -- Secondary



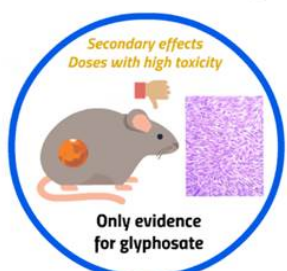
Genotoxic DNA reactive tumour initiation

Weak genotoxin, chromosome effects, secondary



Tumour promotion

*Disrupt repair mechanisms
Promote malignancy*




*Secondary effects
Doses with high toxicity*

Only evidence for glyphosate

3. EFSA considers that the only evidence for carcinogenicity and genotoxicity is for secondary effects at high toxic levels

3




2. HAZARD CHARACTERISATION: POTENCY ASSESSMENT

1. Which effects?
 - All adverse effects relevant for humans
 - Also those not leading to classification
2. At which level of exposure?
 - Dose inducing each relevant effect
3. Selection of the "**critical effect**" for risk assessment
 - Adverse effect occurring at the lowest level

■ A risk assessment "preventing/confirming" this effect will also "prevent/confirm" all other adverse effects

4



**2. HAZARD CHARACTERISATION:
SELECTION OF REFERENCE VALUES**

Relevant toxicity endpoints
mg/kg body weight (per day)

- *Mice tumour trends:* 1000-4800
- Rat neurotoxicity NOAEL: 1546
- Rodent reproductive NOAEL: 300
- Dog short-term NOAEL: 300
- Mice overall NOAEL: 150
- Rat overall NOAEL: 100
- **Critical endpoint: Rabbit NOAEL: 50**
(maternal and developmental, also relevant for short-term exposures)

Toxicological reference values (ADI & ARfD): 0.5

5




3. EXPOSURE ASSESSMENT

1. Representative crops (EFSA Conclusion)
 - Weed control
 - Facilitating harvesting
2. Exposure assessment based on actual measurements in food
 - EFSA complementary assessment
3. Human biomonitoring data
 - BfR complementary assessment

- All EU uses, on-going (EFSA Reasoned Opinion)


6



4. CONSUMERS' RISK ASSESSMENT

- 1. Representative crops**
 - Chronic: 3% Acceptable Daily Intake
 - Acute: 9% Acute Reference Dose
- 2. Measured residues in food**
 - Chronic: 0.6 % Acceptable Daily Intake
 - Acute: 23.4% Acute Reference Dose
- 3. Human Biomonitoring**
 - Dietary: 0.1-0.66% Acceptable Daily Intake
 - Non-dietary: 8.4% Acceptable Operator Exp. Level

7




PUBLIC HEALTH ASSESSMENT

Conclusions

- Public health assessment is triggered by toxic effects other than carcinogenicity
- The Toxicological Reference Values proposed by EFSA offer a high level of protection, covering also the effects considered relevant by IARC
- No health concern for European consumers has been detected using three complementary exposure assessments

8

Presentation by Dr Kate Guyton



The Carcinogenicity of Glyphosate

Kate Z. Guyton PhD DABT
Senior Toxicologist
Responsible Officer, Volume 112
Monographs Programme

International Agency for Research on Cancer
Lyon, France

IARC Evaluation of Glyphosate

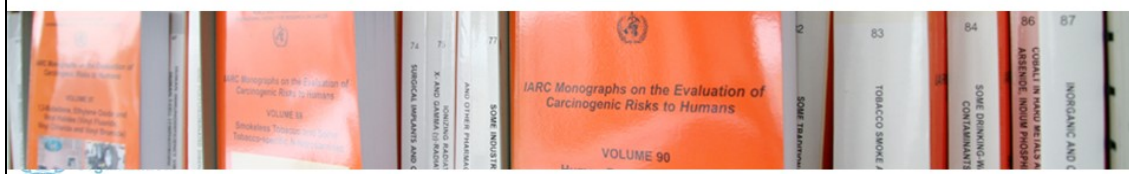
➤ *Probably carcinogenic to humans (Group 2A)*

IARC evaluations are used as a reference worldwide

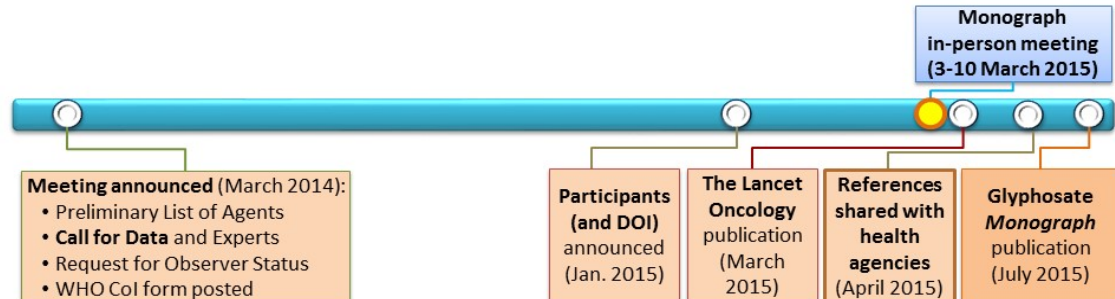
- All data are in the public domain for independent scientific review
- Reviewed by the world's leading experts without vested interests

What happens after IARC identifies a carcinogen?

- Risk assessments help regulators and the public understand the extent of potential cancer risk
- Measures to reduce exposures to workers and to the public



Scientific engagement: Glyphosate *Monograph*



- IARC meetings are open and follow transparent, published methods
- All meeting participants have full access to the data being evaluated
- Fully referenced *Monographs* published on-line for free download

International Agency for Research on Cancer



How was glyphosate evaluated?

- ~1000 studies identified and screened
- **Laboratory studies**
 - "Pure" glyphosate, glyphosate formulations
 - Cancer in mice, rats
 - DNA damage (genotoxicity)
- **Human studies** (real-world exposures)
 - DNA damage— community residents before and after spraying
 - Cancer in humans— farmers, other workers
 - **Published Monograph: >250 references**



International Agency for Research on Cancer



Human cancer studies (NHL)

Studies of exposed workers provide **"limited"** evidence for NHL (Non-Hodgkin lymphoma, a rare type of cancer)

1) Case-control studies

- Sweden, Canada, US
- **2592 NHL cases**
- **Increased risks**, not explained by other pesticides

2) Cohort study (Ag Health Study)

- US, 2 states
- **92 NHL cases**
- No significant increase in risk



3) Meta-analysis

- Objective method to combine **all studies**
- **Increased risks**

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Cancers in mice fed glyphosate

Positive results in 2 of 2 feeding studies

- **Rare cancers: *extremely important in assessing human risk...*** but challenging to detect signal from background noise
 - High statistical significance
 - Benign, malignant cancers; no toxicity
- Evaluation fully in line with accepted principles
- Sufficient evidence of cancer in animals

International Agency for Research on Cancer



Summary: glyphosate hazard evaluation

Cancer in humans (NHL)

Limited evidence

- Studies of real-world exposures (occupational)
- **Glyphosate formulations** in different regions at different times

Cancer in animals

Sufficient evidence

- Studies of pure **glyphosate**
- Rare cancers in valid studies

DNA damage & oxidative stress

Strong evidence

- Few studies of real-world exposures (communities)
- Experimental studies of pure **glyphosate**
- Experimental studies of **glyphosate formulations**



Overall evaluation of glyphosate:

Group 2A Probably carcinogenic to humans

What happens next?

A. What usually happens after IARC classifications?

- A risk assessment- to help understand level of risk with exposure in different settings
- Public health action to limit exposure to workers and the general public

B. Does IARC make policy recommendations?

No. It remains the responsibility of national and international agencies to limit exposures to carcinogens identified by IARC.

Looking to the future...

How to increase transparency in evaluating cancer in animals?

- Reduce potential for publication bias
 - Improve quality of reporting
 - Enhance public disclosure
- Register studies in advance
 - Rationale for design and dose selection
 - Clear methods for analysis and reporting
 - Pathology Working Group peer review
 - Clear identification of experts and any COI
 - Public data availability
 - Study and historical data (pathology, growth curves, survival) for free download

International Agency for Research on Cancer



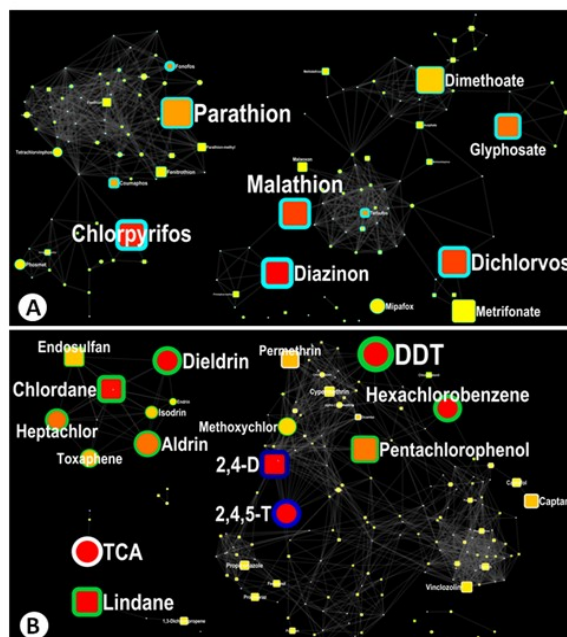
Looking to the future...

How to prioritize pesticides for cancer hazard evaluation?


- Comprehensive list of pesticides
- Automated text mining of public databases
- Data visualization by chemical class

<http://ehp.niehs.nih.gov/EHP186/>

International Agency for Research on Cancer



Presentation by Dr Jack de Bruijn




ECHA
EUROPEAN CHEMICALS AGENCY

ECHA's Evaluation of glyphosate

Workshop: EU's pesticide risk assessment system: the case of glyphosate

Jack de Bruijn, Director
Risk Management Directorate
European Chemicals Agency

24 May 2016



Outline

- CLP Regulation (1272/2008/EC)
- Harmonised classification and labelling (CLH) process
- CLH process
- Glyphosate evaluation
 - State-of-play
 - Next steps

CLP Regulation




- Implements the UN Global Harmonised System (GHS) for classification and labelling in the EU
- Aims to ensure a high level of protection of human health and the environment (e.g. through downstream legislation or resulting labelling and precautionary measures)
- Based on **hazardous properties** of the (active) substance only, not risk
- Is applied to plant protection products, biocides, industrial and consumer chemicals
- Contains a list of ~ 4500 chemicals with harmonised classification and labelling (CLH)

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CLH Process

Main actors:

-  Dossier submitter (Member state CA or industry)
-  Parties Concerned including other MSCAs, industry and NGOs
-  ECHA's Committee for Risk Assessment
-  European Commission
-  ECHA Secretariat accordance check and administrative support



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The Committee for Risk Assessment

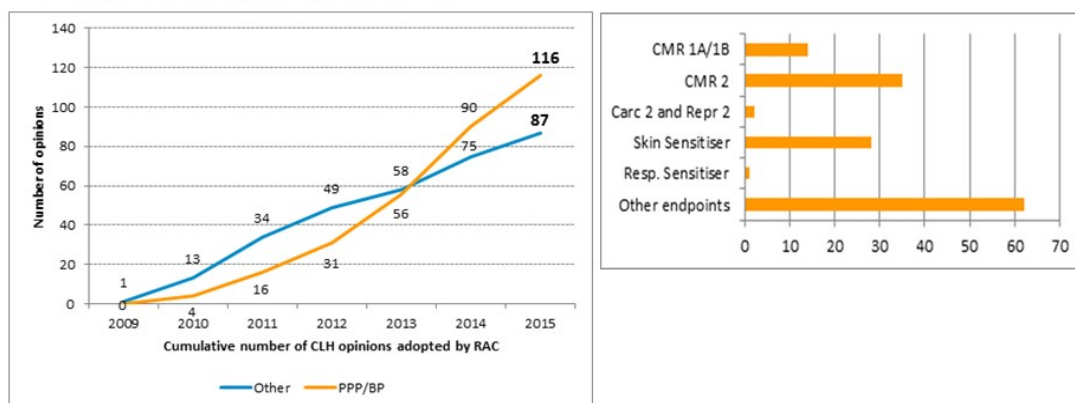
- Scientific opinions on the harmonised classification are prepared by the **ECHA Committee for Risk Assessment** (RAC)
- The 50 members of RAC are independent scientists appointed by ECHA's Management Board based on nominations by the Member States Competent Authorities (MSCAs)
- Taking into account comments submitted during public consultation, RAC assesses the CLH proposals, issues an opinion and submits its opinion to the Commission

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CLH Process to RAC Opinion

Cumulative number of opinions adopted by RAC and CMR properties



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Glyphosate: CLH proposal by the German competent authority

	CLP Regulation
Current entry in Annex VI, CLP Regulation	Eye Dam. 1, H318 Aquatic Chronic 2, H411
Current proposal for consideration by RAC	STOT RE 2, H373
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Eye Dam. 1, H318 STOT RE 2, H373 Aquatic Chronic 2, H411

- The CLH dossier includes new data and reassessment of most hazard classes, including for carcinogenicity, mutagenicity and toxicity for reproduction (CMR)
- Proposal for other health endpoints, including "CMR": No classification




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CLH Process

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Glyphosate state-of-play

- Rapporteurs have been appointed in accordance with the REACH Regulation governing the ECHA Committees and Committee's Rules of Procedure
- ECHA secretariat:
 - has checked the CLH dossier for accordance (e.g. correctness of the comparison with CLP criteria)
 - but provides **no opinion on the C&L proposal**
- CLH dossier has been revised by the German competent authority
- Launch of public consultation currently planned for early June

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Glyphosate: next steps

- **Public consultation: 45 days**
 - Anticipating large number of comments
 - Responding to comments by the dossier submitter (DE CA)
- **Opinion development: 2-3 months**
 - First presentation to RAC possibly in December 2016 (RAC-39)
 - Foreseen adoption at RAC meetings in March/June 2017
- ECHA fully committed to work together with all involved authorities and interested parties

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Thank you

Jack.DE-BRUIJN@echa.europa.eu>

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Presentation by Dr Pierre Lebailly



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UNICANCER
Centre
de Lutte contre le Cancer
François
Baclesse

« AGRiculture & Health Risk, French experience »

**EU's pesticide risk assessment system:
the case of glyphosate**

Brussels – 24th May 2016



Background

Cancers in agriculture ?

- Lower risk for some cancers, especially those associated with smoking
- Higher risk for some others (prostate, lip, melanoma, hematological, brain...)

Cancers related with specific pesticides ?

- To deal with assessment of **exposure** ? Type ? Level ?
- To deal with **mechanisms** of cancer not well known ?
- Level of **Hazards** of pesticides ?
Data from regulation and from peer-reviewed literature...

Exposure to pesticides ?

- No gold standard to :
 - identify **people** exposed (to specific pesticides)
 - quantify **level** of exposure
- Occurs ! Not characterized for some types of application
and for many tasks during agricultural activities

Background

Exposure to pesticides (data from field studies/questionnaires) ?




Which **tasks** ?


- **Personal use of pesticides** ? 69% Men / 17% Women
 - **Mixing/loading** ? OF > 80% ; Grapes > 30%
 - **Applications** ? OF < 20% ; Grapes > 50%
 - **Cleaning** of sprayer ? OF ? ; Grapes > 20%
- Insecticides on **animals** ? 37% Men / 12% Women
- Herbicides between **crops** ? ???
- Herbicides on **farmyard** ? 57% Men 19% women
- Re-entry tasks on **crops/animals** ? Up to **100%** !
- **Secondary** exposure with equipment, tractors, farmyard...
(sprayer, tractor, farmyard, clothes, PPE...) ?
- **Living** on a farm ? Close to **fields** ?


...


Baldi et al **2006**; Lebailly et al **2009**; Baldi et al. **2012**; Baldi et al **2014**


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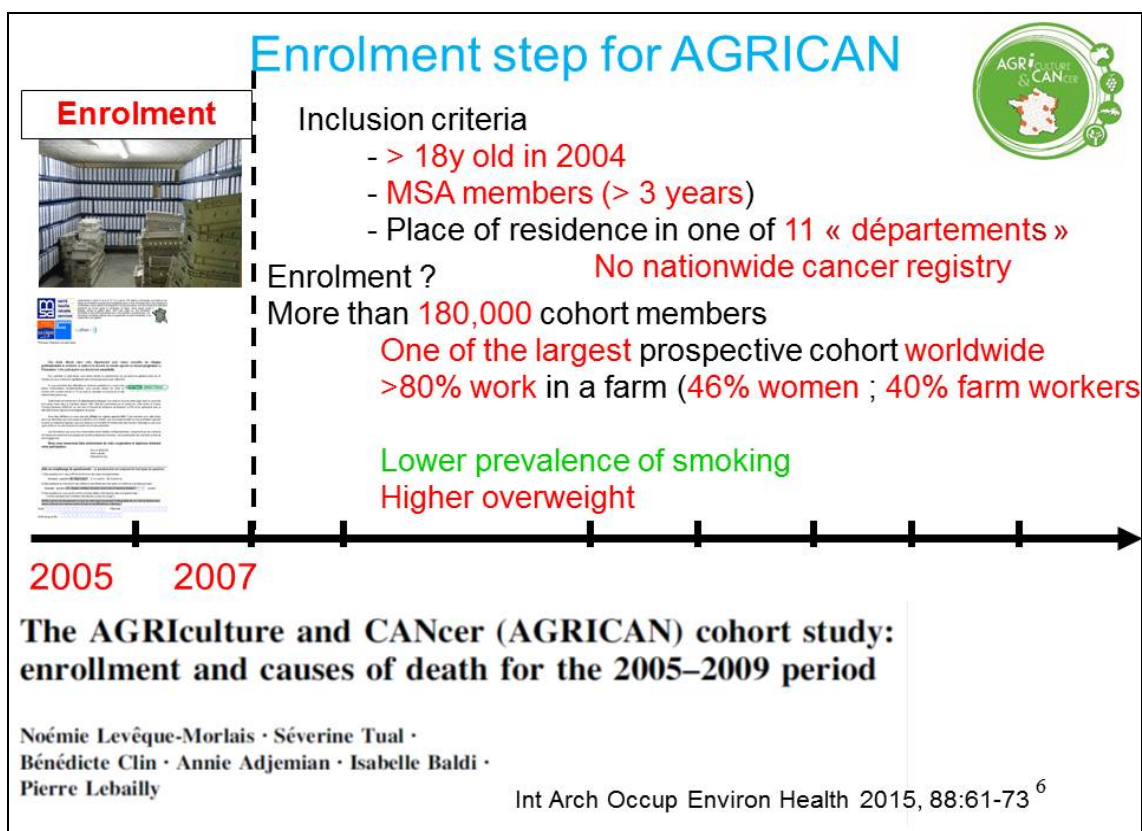


AGRICAN cohort ?

Main objectives:

- i) **Cancer** risk related with agricultural **activities**
(crops, livestock, tasks)
- ii) **Improvement** in **exposure knowledge** and **assessment**
on pesticides (use, re-entry, harvest...) and other hazards
- iii) Effects on **less studied population**
(women, farm workers, seasonal/migrant?) with sufficient **statistical power**





Enrolment step for AGRICAN



13 crops (2 to 5 tasks, years, areas)

Grasslands (64% vs 42%)

Wheat/barley (55% vs 24%)

Grapes (35% vs 31%)

Corn (43% vs 13%)

Potatoes (25% vs 25%)

Beets (21% vs 14%)

Fruit growing (18% vs 17%)

Field vegetables (9% both)

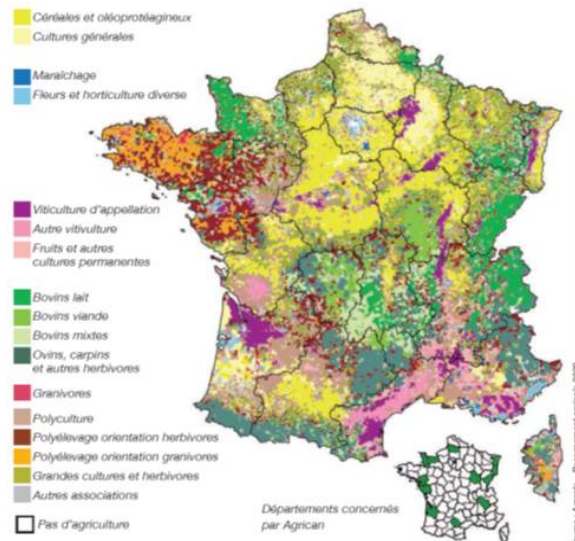
Greenhouses (4% both)

Rape (12% vs 3%)

Peas (8% vs 3%)

Sunflower (10% vs 2%)

Tobacco (9% both)



7

Levêque-Morlais et al. Int Arch Occup Environ Health 2015

Enrolment step for AGRICAN



Pesticide use for each crop by sex

	Women	Men
- Any crop	17%	69%
- Grasslands	11%	38%
- Grapes	10%	60%
- Wheat/barley	9%	62%
- Corn	12%	80%
- Beets	5%	38%
- Peas	10%	58%
- Sunflower	18%	71%
- Rape	14%	67%
- Tobacco	18%	52%
- Fruit growing	7%	36%
- Potatoes	7%	37%

8

Follow-up in AGRICAN



Health endpoints:

- Vital status (MSA, RNIPP)
 - Causes of death (CépiDC)
- } **annually since 2009**
- Cancer incidence (population based cancer registries)
Every 2-years since **2012**

Other endpoints: exposures...

- Residential location (MSA, La Poste) annually since **2009**
- Work in « agriculture » (MSA)
- Agricultural activities, potential confounding (life habits...)
first follow-up questionnaires (Step began in **2016**)

9

Comparison with general population

Cancer incidence for the 2005-2011 period



	AGRICAN – Men (N)	AGRICAN – Women (N)
All Cancers	0.99 (7,304)	0.98 (3,763)
Lung	0.58 (625)	0.6 (150)
Bladder	0.67 (278)	0.79 (60)
Colon	0.87 (609)	0.95 (424)
Prostate / Breast	1.07 (2,538)	0.90 (1 087)
Lip / Ovary	1.38 (27)	1.06 (145)
Cut. melanoma	0.96 (178)	1.23 (169)
NHL :	1.09 (644)	1.05 (367)
MM	1.38 (157)	1.26 (97)
DLBC	1.12 (116)	0.97 (70)
FL	0.67 (29)	1.03 (33)
T/NK L	1.16 (40)	1.40 (24)
Hodgkin Disease	1.28 (24)	1.10 (10)

Lemarchand et al. To be submitted

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Internal analyses



- / type of agricultural **activities and tasks** (including pesticides)
- / Effects of specific pesticides through crop exposure matrix **PESTIMA1?**

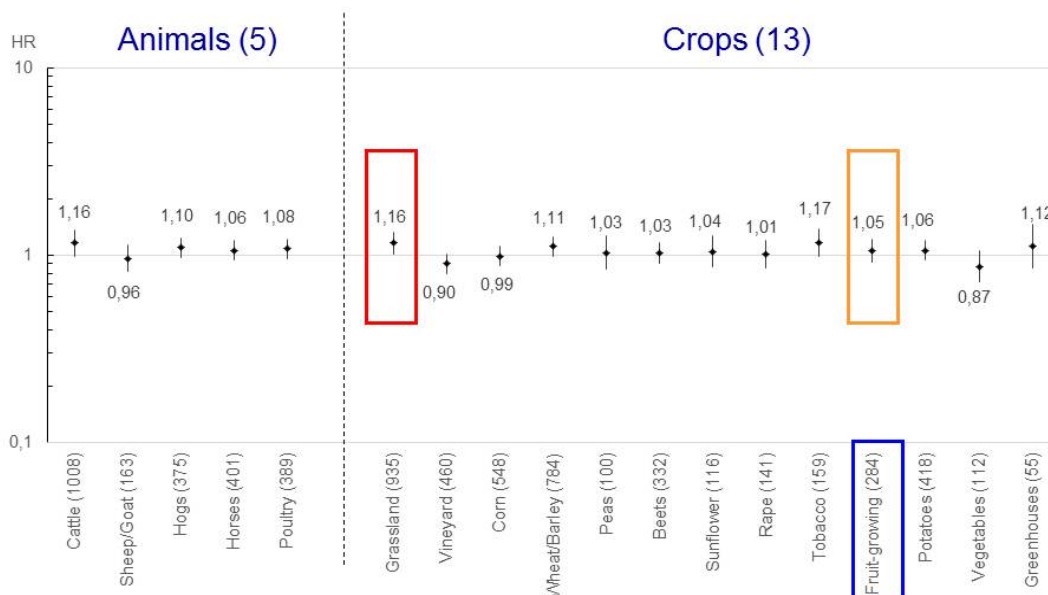
a) Respiratory diseases

- **Chronic Bronchitis** (Tual et al., Annals Epidemiol 2013)
- **Asthma** (Baldi et al., Int J Hyg Environ Health 2014)

b) Cancers

- **Lung** (**Cattle and Horses**, insecticides on livestock, peas, vegetables)
Tual et al. (Submitted) ; Boulanger et al. (In preparation)
- **Prostate** (**Cattle, grassland, fruit growing, potatoes and tobacco**)
Lemarchand et al (Scand J Work Environ Health 2016)
- **Prostate – Organochlorine insecticides** (8 out of 17, cyclodienes)
Lemarchand et al (in preparation)
- **Breast** (**Cattle, wheat, peas, beets, vegetables, insecticides**)
before menopause: higher risk)
Lemarchand et al (in preparation)
- **Bladder** (**vegetables, greenhouses, peas and rape, women**)
Boulanger et al (submitted)
- **Hematological cancers** (Brouwer et al. 2016, 4 in preparation)
(**AGRICOH** with AHS and Norwegian census: > **3,000 cancers**)¹¹
- **Brain** (Meningioma: **peas, beets, sunflower, hogs** ; Glioma: **trends**)¹¹

Internal analyses (ex: prostate cancer)



Lemarchand et al. Scand J Work Environ Health 2016, 42:144-52.

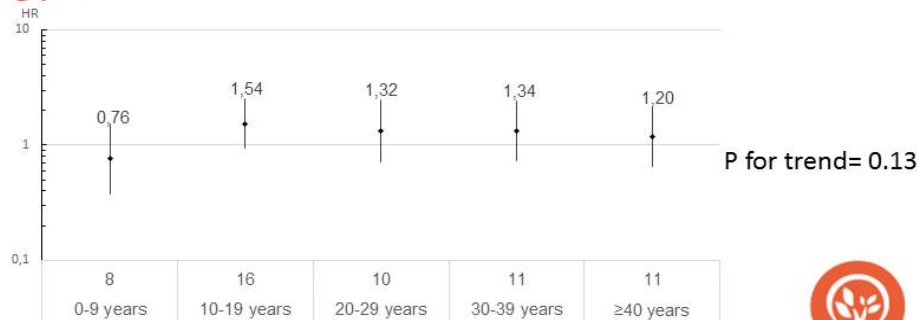
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Internal analyses (ex: prostate cancer)

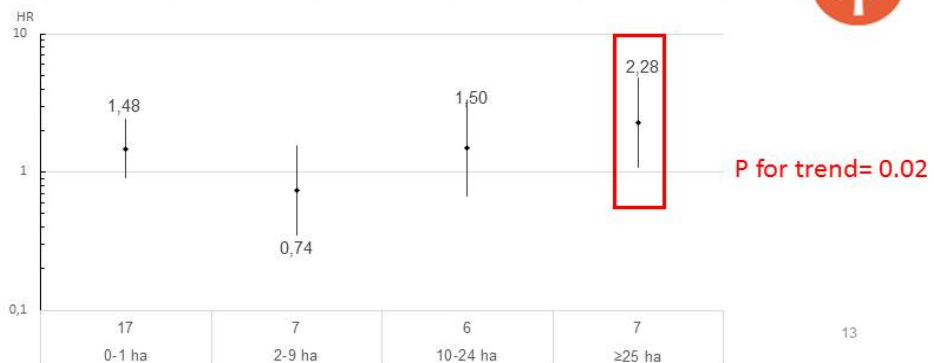


Fruit growing pesticide use

Duration:

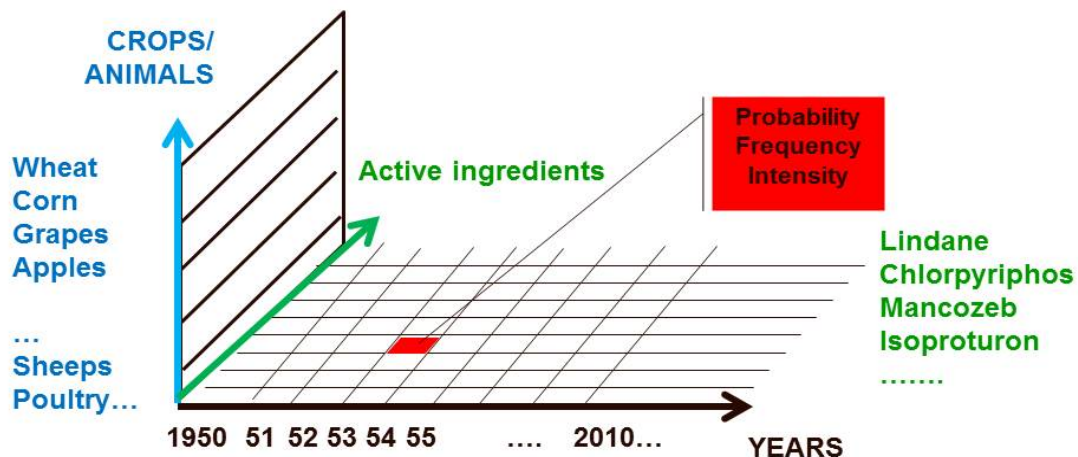


Surface:



PESTIMAT : aim and general feature

Aim : To elaborate a **crop** (livestock) – **exposure matrix** enabling **historical** reconstitution of **pesticide** exposure in main French agricultural settings.



Baldi et al. J Expo Sci Environ Epidemiol. 2015 Dec 23

PESTIMAT					
Progress					
Wheat/barley, Vineyards, Corn, Fruit-Growing					
Data collected for 554 active ingredients					
INSECTICIDES N=228		HERBICIDES N=156		FUNGICIDES N=170	
Chemical groups	N	Chemical groups	N	Chemical groups	N
Arsenicals	5	Chloroacetamids	5	Strobilurines	9
Carbamates	19	Dinitroanilines	5	Dithiocarbamates	12
Organochlorines	19	Diphenylethers	7	Carbamates	5
Organophosphates	78	Thiocarbamates	10	Inorganic	31
Pyrethroids	24	Phenoxyherbicides	10	Phtalimides	6
Neonicotinoids	4	Triazines	9	Dicarboximides	5
Benzoylureas	6	Nitriles	5	Morpholines	2
Others*	73	Ureas	12	Triazoles	25
		FOPs & DIMs	12	Benzimidazoles	4
		Bipyridiles	2	Others*	71
		Sulfonyl ureas	19		
		Others*	60		

Baldi et al. J Expo Sci Environ Epidemiol. 2015 Dec 23

PESTIMAT : organochlorine insecticides

25 Ocs
between 1950 and 2010

On 6 crops:

- Vineyard
- Wheat/Barley
- Fruit growing
- Corn
- Rape
- Potatoes

Included (IARC)	Excluded
Aldrin (3)	Chlordecone
Chlordane (2B)	Perchlordecone
Dieldrine (3)	Diénochloro
Heptachlor (2B)	B-HCH
DDD (NC)	Hexachlorocyclopentadiene
DDT (2A)	Kelevan
Methoxychlor (3)	Pentachlorophenol
Perthane (NC)	
Endosulfan (NC)	
Toxaphene (2B)	
HCH (2B)	
Lindane (1)	
SPC (NC)	
Chlorofenethol (NC)	
Chlorobenzilate (NC)	
Chloropropylate (NC)	
Dicofol (3)	
Bromopropylate (NC)	



Internal analyses (ex: prostate cancer)

Effect of organochlorine insecticides ?

	N cases	HR	95% CI	duration P for trend
Vineyard	168	1.17	0.97-1.41	0.44
Wheat/Barley	271	1.16	0.99-1.37	0.32
Fruit-growing	55	1.25	0.94-1.66	0.10
Corn	226	1.11	0.94-1.32	0.54
Rape	56	1.30	0.98-1.73	0.05
Potatoes	123	1.30	1.06-1.60	0.07



Perspectives

Difficulties to face ?

- Missing data (multiple imputation, f-up questionnaires..)
- Multiple exposure
- Exposure to specific pesticides (during re-entry tasks, livestock...)
- New results confirmed by others ?

Look to hazards, their levels ? Through field studies !?

Strength ?

- Largest study worldwide
- Almost all agricultural activities/tasks
- Design of questionnaires from field studies
- Original information on :
 - various tasks with historical data, farm workers, women, exposures
- Possibility to study rare cancers
 - other diseases (respiratory, neuro., birth-cohort...)



Collaborations:

EPICENE, Francim, MSA

AGRICOH / NCI

Grants?

Enrolment step :

MSA, French League Against Cancer, ANSES, Conseil Régional Normandie

ARC, Centre F Baclesse, Fondation de France, InCA,

Conseil Général du Calvados, UIPP

Health Follow-ups

MSA, French League Against Cancer, ANSES (ONEMA), Centre F Baclesse,

UIPP, INMA

Follow-up of exposures

ONEMA (Ecophyto), French League Against Cancer, MSA

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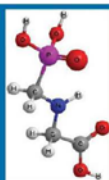
Presentation by Prof Dr Xavier Baur



Workshop: EU's pesticide risk assessment system:

The case of

GLYPHOSATE



Options based on clinical daily practice

Prof. Dr. Xavier Baur

Charité Institute for Occupational and Medicine Berlin, Germany
European Society for Environmental and Occupational Medicine, EOMSociety

X. Baur EP, Gyphosate Workshop May 24, 2016

Options based on clinical daily practice: Overview

- Bio-Scetch
- Specific adverse health effects of glyphosate in humans
- Clinical daily practice in environmental an occupational medicine with special regard to agricultural settings
 - Malignant tumors: latency periods and dose-response relations
 - The human innate defence system: it did not gain experience with man-made carcinogens
- Conclusions

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Bio-Sketch

Xaver Baur, M.D., Senior Professor, Charité University Clinic Berlin, Institute for Occupational Medicine, Germany (2012- present).

Initiator and current president of the charity European Occupational and Environmental Medicine Society [www. EOMSociety.org](http://www.EOMSociety.org)

1961-1969 primary education and training in **farming**

1969-1990 secondarily, medical training, University of Munich, Germany with qualification in **Internal Medicine, Pneumology, Allergology, Cardiology, Occupational and Environmental Medicine**

1990-2012 chair in Occupational Medicine Departments at the Universities of Hamburg, and Bochum, and director of Institutes for Occupational Medicine at universities of Hamburg and Bochum

Focus of clinical and research: diagnostics, management, prevention of work-related disorders; health of agricultural, dock and construction workers, miners; ethical issues related to occupational medicine).

Fellow of the Collegium Ramazzini. (Advisory) board member of several scientific journals, e.g. of The Lancet Respiratory Medicine

I do not have any conflict of interest in this issue

Glyphosate evaluation (EFSA vs IARC) (I)

	EFSA	IARC
<u>General</u>	C. 100 anonymous experts. Possible financial support, COI declaration and affiliations not disclosed. Citations for most references removed. Peer-reviewed studies received less weight than guideline studies/Good Laboratory Practice. Anonymous letters considered	Full disclosure; transparent and rigorous process by 17 indicated independent experts. Evaluation of all/and only of publically available studies

Glyphosate evaluation (EFSA vs IRAC) (II)

	EFSA	IRAC
<u>Animal carcinogenicity</u>	<p><i>no evidence</i></p> <p>“The Mysterious Three” confidential industry studies described by José Tarazona, head of EFSA's Pesticides Unit, as “key” and “pivotal”</p> <p>EFSA had access also to at least three</p>	<p><i>sufficient evidence</i></p> <p>Kidney tumors and hemangiosarcoma in 2 studies</p> <p>IARC either only had access to summaries of these mysterious studies which were lacking key information, or no access at all (since they are unpublished, confidential documents)</p>

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Glyphosate evaluation (EFSA vs IRAC) (III)

	EFSA	IRAC
<u>Human carcinogenicity</u> case-control studies	<p><i>unequivocal</i></p> <p>“not reliable”</p>	<p><i>limited evidence</i></p> <p>“reliable”.</p> <p>2 meta-analyses considered</p>
<u>DNA, oxydative stress</u>	<p><i>devoid of genotoxic potential</i></p> <p>Chromosomal studies not considered</p>	<p><i>strong evidence</i></p> <p>All scientifically rigid studies considered</p>
<u>Overall</u>	<i>unlikely</i>	<i>probable carcinogen</i>

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IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112 (2015)

Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos

Glyphosate - Human cancer:

- Positive association between glyphosate and NHL in
 - 4 pooled case-control studies
 - 2 additional case-control studies
- 2 positive meta-analyses
- Studies of higher quality adjusted for multiple exposures
- Length of exposure increased the strength of association
- Chance, bias and confounders not completely ruled out

➤ **limited evidence of causality**

➤ **when combined with animal and in-vitro studies: possible human carcinogen**

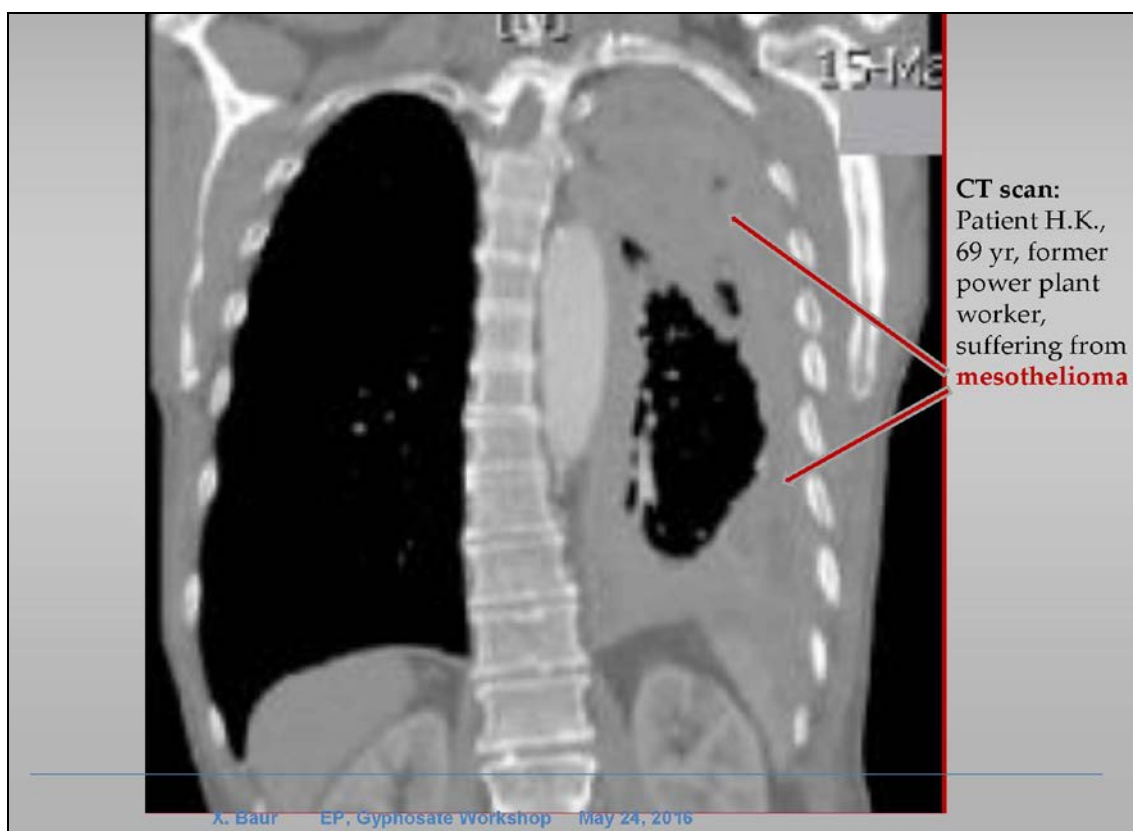
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Experiences in our clinical daily outpatient practice (I)

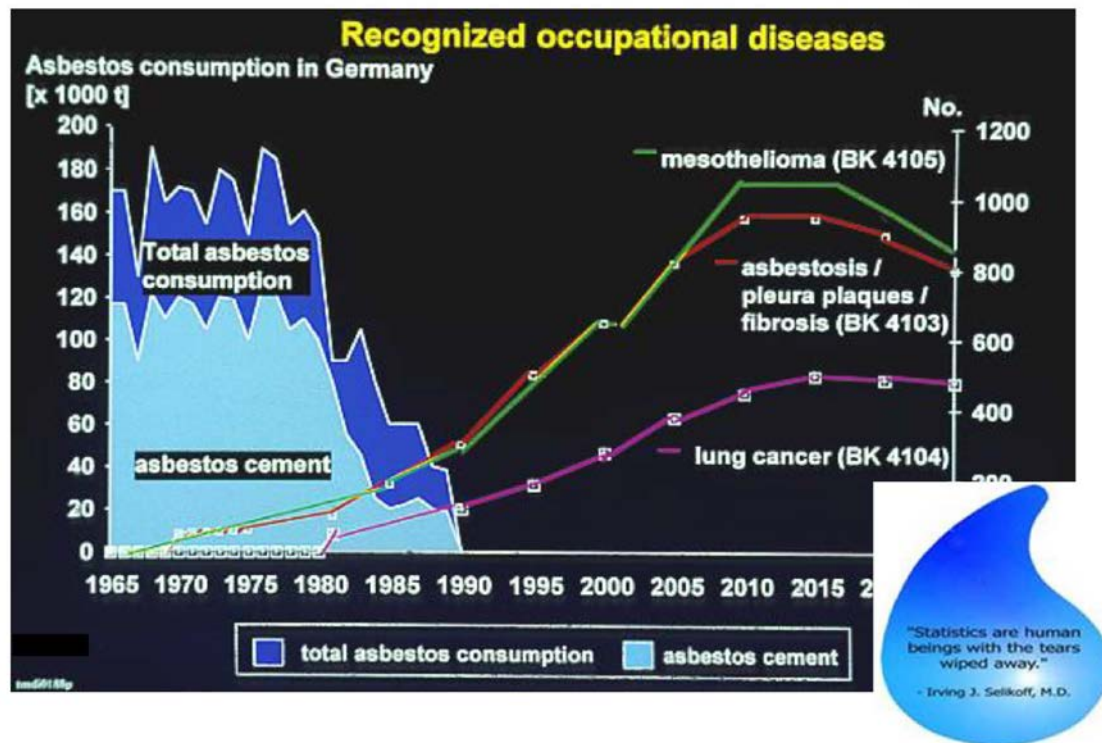


- Allergic or irritative skin ekzema
- Asthma and COPD due to environmental exposures, smoking
- Lung cancer and mesothelioma due to asbestos (*„the most expensive erroneous decision of the industrial society“*)

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Latency periods between asbestos exposure and disorders (Germany)



Source: **The Human and Financial Burden of Asbestos in the WHO European Region**, Meeting Report. Copenhagen: WHO Regional Office for Europe
<http://www.euro.who.int/en/media-centre/events/events/2015/04/ehp-mid-term-review/press-and-media/at-least-one-in-three-europeans-can-be-exposed-to-asbestos-at-work-and-in-the-environment/annex-total-costs-of-mesothelioma-cases-in-15-european-countries-in-one-year>

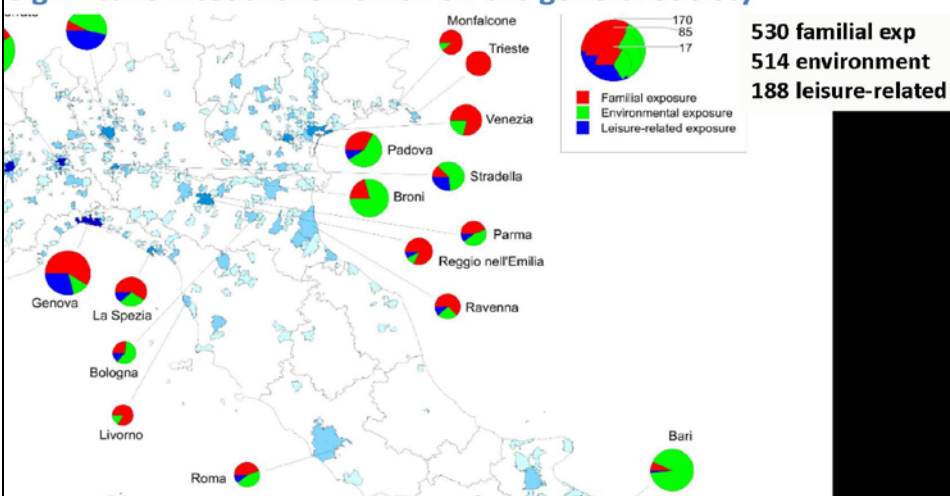
Table 5.2.4. Total costs of mesothelioma cases in 15 European countries in one year

Country	No. of mesothelioma cases (underestimates)	Total costs ^a (€)
Austria	80	21 035 120
Belgium	156	41 018 484
Denmark	71	18 668 669
Finland	75	19 720 425
France	826	217 187 614
Germany	1 063	279 504 157
Italy	1 235	324 729 665
Netherlands	395	103 860 905
Norway	54	14 198 706
Poland	96	25 242 144
Portugal	19	4 995 841
Romania	58	15 250 462
Spain	263	69 152 957
Sweden	123	32 341 497
United Kingdom	1 891	497 217 649
Total		1 684 124 295

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Workshop May 24, 2016

^a Pensions and acute medical costs, excluding primary/palliative care = €262 939 per case. The total costs assume that German pensions do not include medical treatment costs.

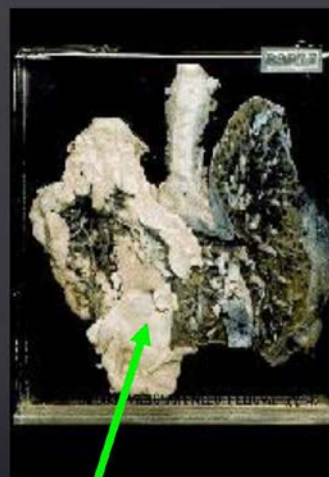
Environmental asbestos contamination poses a significant mesothelioma risk on the general society



Marinaccio et al. 2014: Italian ReNaM: Among the **15 845 mesothelioma cases** registered between 1993 and 2008, exposure to asbestos fibres was investigated for 12 065 individuals (76.1%), identifying 530 (4.4%) with familial exposure (they lived with an occupationally exposed cohabitant), 514 (4.3%) with environmental exposure to asbestos (they lived near sources of asbestos pollution and were never occupationally exposed) and 188 (1.6%) exposed through hobby-

In spite of asbestos –Early Medical Findings

- ✎ **1918** - MetLife insurance recognized increased mortality in asbestos workers, but distorted medical literature
- ✎ **1920s** - More than 25 published articles concerning asbestos and lung disease
- ✎ **1931** - 172 Cases reported in Literature; Klemperer and Rabin used the term "mesothelioma"



Mesothelioma

R. A. Lemen, Ph.D., modif.

and the world-wide pandemic, the asbestos industry still trivializes or even denies health risks

Experiences in our clinical daily outpatient practice (II)

Disorders in farmers and agricultural workers:

- various cancers, esp. NHL, bladder cancer
- polyneuropathia
- farmers' lung disease, COPD



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Case report: T.H., male, 74 yr

Occupational history

- 1953-1996 working on different farms (diary, pigs, cereals, sugar beets, potatoes)
- Application of various herbicides and pesticides, especially in cultivation of grain on a large scale
- No preventive measures. PPD not used

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Case report: T.H., male, 74 yr

Clinical history

2009 Diagnosis of abdominal Non-Hodgkin's-Lymphoma

Treated by operation plus chemotherapy (6 cycles), resulting in complete remission

Cause:

Cumulative pesticides? Glyphosate? Genetic? Unknown?

Be aware of latency period of decades resulting in missing the causative agent. Clinicians realize associations rather late
Epidemiological studies are needed.

X. Baur EU, EFSA Meeting May 24, 2016



What is Non-Hodgkin's lymphoma (NHL)?

Non-Hodgkin's lymphoma (NHL) is a cancer of the lymphatic system. It is characterized by the presence of cancerous lymphocytes in lymph nodes; the disease can spread to other parts of the lymphatic system, i.e. to lymphatic vessels, tonsils, adenoids, spleen, thymus, bone marrow. Other organs may also be involved.

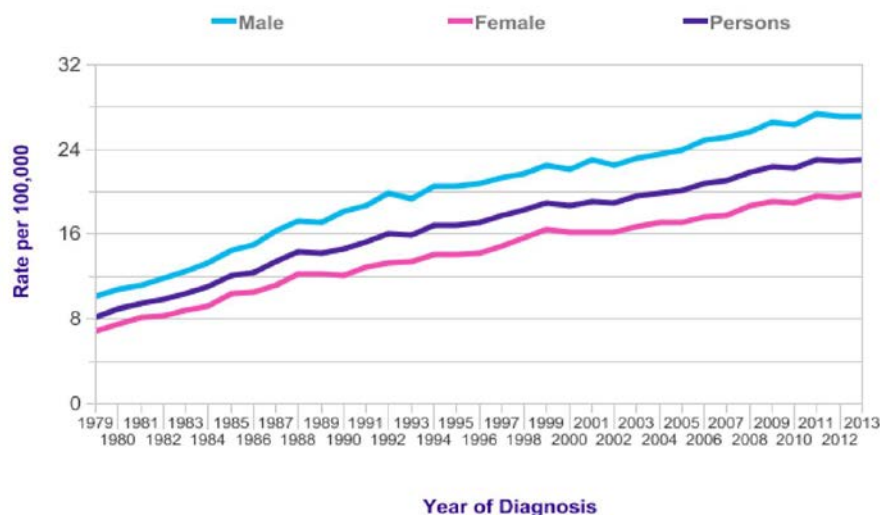
Symptoms: Swelling of lymph nodes, chest or abdominal pain, cough, shortness of breath, fatigue, fever, night sweats, weight loss

Prognosis: variable, c. 50 % survive 5 yrs

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Increase in Non-Hodgkin's Lymphoma

Non-Hodgkin Lymphoma (C82-C86): 1979-2013
European Age-Standardised Incidence Rates per 100,000 Population, by Sex, Great Britain



Source: cruk.org/cancerstats



Conclusions

- Lessons learned from the asbestos pandemic killing 10 million people world-wide (WHO) – Especially, trivializing or even denying proven health risks of interest groups; see the parallelism with the current situation
- Glyphosate and its formulations represent new potentially hazardous external and internal loads of the human body; their health risk is incalculable at present
- Based on experiences with other environmental carcinogens precaution is strongly recommended: there should be no contamination of everyday food, beverages, the environment, since cumulative long term effects may occur
- Not only after the asbestos pandemic and the diesel affair it is evident that current practice of risk evaluation of potentially endangering agents does not sufficiently protect health of European workers and citizens and the environment
- You as EPMs have a high responsibility for the health of the next generations: do not pose an incalculable risk on them


X. Baur EU, EFSA Meeting May 24, 2016

Thanks for your attention

Merci pour votre attention

X. Baur EP, Glyphosate Workshop May 24, 2016

Presentation by Ms Génon Jensen



Approaches to Management of Glyphosate and Disease

A NGO view

Genon Jensen
Health & Environment Alliance (HEAL)
European Parliament ENVI Workshop
**EU's Pesticide Risk Assessment:
The case of Glyphosate**
24 May 2016

HEAL's member network

>70 organizations
in 28 countries

- Doctors associations
- Patient groups
- Nurses associations
- Public health institutes
- Research institutes
- Not-for-profit health insurers
- Women's groups
- Youth groups
- Environmental groups



*Promoting environmental policy
that contributes to good health*



Science on Glyphosate

- Increased human exposure → reason for caution
- Longer persistence in environment → reason for caution
- Carcinogenicity → illegal in the EU
- Effects on Nutrient balance → health impacts
- Possible Endocrine Disruption → if, then illegal in EU



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Science on Glyphosate

IARC v EFSA

In EU – minimum for **carcinogenicity**:

- Sufficient evidence in 2/more animal species
- OR in 2/more separate studies

→ **FOUND**
but wrongly dismissed

94 scientists say **EFSA/BfR analysis** is

- “scientifically unacceptable”
- “fundamentally flawed”
- “misleading”



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Science on Glyphosate

Scientists' Consensus Statement, Feb 2016

"Collectively, studies from lab animals, humans and domesticated animals suggest that **current levels of exposure** to glyphosate-based herbicides can **induce adverse health outcomes**"



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Science on Glyphosate

Scientists' Consensus Statement



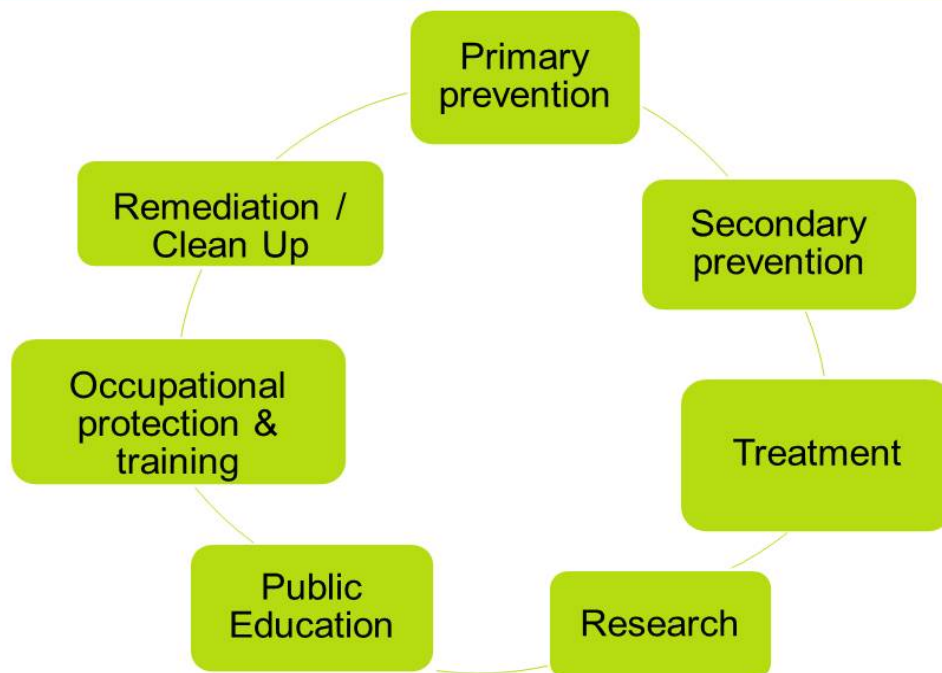
"The current EU ADI is probably at least **three-fold too high**, based on a transparent, fully documented review of the same data"



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Managing & Preventing Disease



Primary Prevention – Safer Alternatives

Integrated Pest Management

The law in Europe in effect since Jan 2014
(Sustainable Use Directive 2009/128/EC)

Member states to ensure farmers have

- Information & tools to monitor pests + decide on measures
- Advisory services on integrated pest management



➔ **IS THIS HAPPENING?**

Primary Prevention - Reduce Exposure

Address **outdated TDIs** (Scientific consensus statement)

Strict **limits on pre-harvest use** (EP Resolutn, Art 2)

Stop use by non professionals (EP Resolution, Art 2)

Stop use in / near public parks/playgrounds
(EP Resolution, Art 5)

Stop use where IPM sufficient for weed control
(EP Resolution, Art 6)

Finance research & innovation for alternative sustainable solutions
to pest managemt (EP, Art 11)



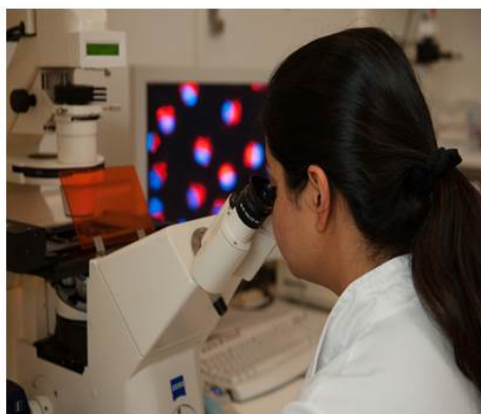
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Civil Society Views

*"IARC's findings suggest that
**banning glyphosate should
be part of Europe's cancer
prevention policy**"*

- European Cancer Leagues



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Civil Society Views



French Cancer
League



Portuguese Medical
Association



Flemish Cancer
League (Kom Op)



Cancer Prevention
& Education Society
(UK)



Breast Cancer UK



Malta Action Against
Breast Cancer
Foundation

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Conclusions

Approving glyphosate

- Against EU law
- Against the public will
 - 2/3 of public doesn't want glyphosate used
- Probable long term public health consequences
 - More non Hodgkin Lymphoma in later decades, with 50% mortality rate, and other health impacts
- **Failure of societal CANCER & OTHER DISEASE PREVENTION**
 - Individuals cannot choose to avoid glyphosate exposure



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What's Next?

- **Public consultation on classification**
at European Chemicals Agency:
 - carcinogenicity,
 - germ cell mutagenicity
 - reproductive toxicity & other hazard classes
- **EU Authorisation = National Responsibility**
for glyphosate containing products
- **EFSA setting Maximum Residue Level**



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Thank you for your attention!

Contact us: info@env-health.org

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NOTES

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT ECONOMIC AND SCIENTIFIC POLICY **A**

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- Employment and Social Affairs
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