

#### **EFSA Pesticides Unit**

## Minutes of the 7<sup>th</sup> meeting of the EFSA Working Group on Operator, Worker, Resident and Bystander Exposure Guidance

TELE-conference, 29 09 2014 (Agreed on 30 09 2014)

#### **Participants**

- Working Group Experts:
  - Claudia Grosskopf
  - Paul Hamey
  - Kiki Machera
  - Sabine Martin
  - Walter Steurbaut
- Hearing Experts:
  - Georgina Downs
- European Commission and/or Member States representatives:
  - none
- EFSA:
  - Pesticides Unit:

Manuela Tiramani (Chair of the WG)
Luc Mohimont (Deputy Head of the Pesticides Unit)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.



#### 2. Adoption of agenda

The agenda was adopted.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest filled in by the experts invited for the present meeting and the Oral Declarations of interests at the beginning of the meeting.

Ms Georgina Downs' role as Founder and Director of the UK Pesticides Campaign represents a conflict of interest under section II (Member of a management body or equivalent structure) in application of article 10 of the above-mentioned Decision of the Executive Director, but this conflict does not exclude or limit her participation as hearing expert.

In his Oral Declaration of Interest Mr Paul Hamey mentioned that the written statements he provided as civil servant to a past Judicial Review of the UK Regulatory Authority's approach to bystander and resident risk assessment were in the context of a legal case between the UK government and Ms Georgina Downs. In application of article 12 of the above-mentioned Decision of the Executive Director, this is not creating a conflict of interest resulting in an exclusion or remedial measure being applied as this is a past activity.

#### 4. Hearing session with Ms Georgina Downs (UK Pesticides Campaign)

A list of questions was developed by the WG based on the comments submitted by Ms Downs during the public consultation.

The Chair of the WG asked the questions developed by the WG. Ms Downs provided oral answers. In addition, she sent those answers in writing during the hearing (see Annex 1). They were circulated by the Chair to the members of the WG at the end of the hearing session.

After Ms Downs completed her oral replies, two clarifications were asked by the WG.

#### 5. Discussion of the WG as follow-up on the hearing session

The WG discussed the answers provided by the hearing expert, to establish if they triggered a need for any change in the current draft Guidance (revised after the public consultation, during the meeting held on 10-12 Sep 2014). In particular the WG assessed if the presented information provided quantitative data which could be used to support any modification of the input parameters currently considered in the calculator.

It was agreed that no additional evidence (i.e. quantitative data) was provided further to that already considered by the WG in the drafting of the current draft Guidance.

#### 6. Any other business

The next steps of the activity were illustrated by EFSA.

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



### **ANNEX 1**

WRITTEN RESPONSES TO THE QUESTIONS ASKED BY THE EFSA WORKING GROUP ON OPERATOR, WORKER, RESIDENT AND BYSTANDER EXPOSURE GUIDANCE

FOR THE HEARING SESSION ON 29TH SEPTEMBER 2014

PREPARED BY GEORGINA DOWNS, UK PESTICIDES CAMPAIGN

## WRITTEN RESPONSES TO THE QUESTIONS ASKED BY THE EFSA WORKING GROUP ON OPERATOR, WORKER, RESIDENT AND BYSTANDER EXPOSURE GUIDANCE

### FOR THE HEARING SESSION ON 29<sup>TH</sup> SEPTEMBER 2014

#### PREPARED BY GEORGINA DOWNS, UK PESTICIDES CAMPAIGN

29th September 2014

WITHOUT PREJUDICE

#### **Introductory comments**

Hello. Before turning to the responses to the questions I would just like to point out that I have only been able to carry out limited work recently due to health problems and as a result the few days that I was given to prepare the responses to the questions asked by the Working Group was simply not enough time in the circumstances. In any event, as far as I am concerned the majority of the questions, if not all, have already been answered in the factual evidence and materials already submitted to EFSA, the PPR Panel, and this Working Group, since 2006, including on the DVD. I hope members have all had a chance to see the 2 videos on the DVD, as well as to consider the various documents that I have submitted to date, including the detailed comments on the draft Guidance.

As agreed last week with the Head of Unit, Jose Tarazona, I have just sent by email, to the Chair of the Working Group, a copy of the document containing the written responses to the questions, with the specific request **not** to distribute the document to the WG members until **after** the end of this agenda item 3.

Please note that due to its length I am unlikely to be able to cover everything verbally that is contained in the written version due to the time element.

## <u>Question 1</u>: Could you please provide exposure data to highlight in what bystander and resident exposure to pesticides differ, further to, e.g., frequency?

The campaign I run the UK Pesticides Campaign has continued to provide to EFSA and the PPR Panel since 2006, as well as subsequently to this Working Group, the real life factual evidence and data (including in numerous written submissions, as well as visual materials such as the two videos on the DVD and

in a number of photos) that clearly shows the differences between bystander and resident exposure to pesticides, as residents have a completely different exposure scenario to a mere bystander and thus residents and bystanders are two separate exposure groups.

Whereas a bystander may receive occasional short term exposure to pesticides, and which will be predominantly to spraydrift, residents living in a fixed position in the locality of pesticide sprayed fields are subjected to a combination of **both** repeated acute exposures and repeated chronic exposures, from a number of exposure sources (such as exposure to droplets, particles and vapours at the time of the applications, as well as in the air in the days, weeks and months after the applications, exposure via: contaminated surfaces both inside and outside, precipitation, reactivation, tracking indoors from outside, dust (including harvesting dust), pollen, long range transportation), and exposure routes (such as inhalation, dermal, oral, and eyes), and this specific exposure scenario for residents will be to innumerable mixtures and combinations of different pesticides (and other chemicals that may be in the formulation(s)) sprayed on fields in the locality of residents' homes, over many years and in some cases, like my own situation, for decades. A transient bystander occasionally exposed to pesticides clearly does not have this specific type of exposure scenario. Therefore the differences between these two separate exposure groups of residents and bystanders could not be clearer.

The UK Pesticides Campaign has correctly continued to point out that residents living in locality of sprayed fields are a group with one of the highest levels of exposure to pesticides, considering the frequency and duration of exposure, as well as cumulative exposure, from a number of exposure sources and exposure routes, to innumerable mixtures of pesticides, repeatedly sprayed, in the locality of residents' homes, throughout every year, and in many cases, for decades.

As I highlighted in both the UK Pesticides Campaign's summary and detailed comments on the EFSA draft Guidance, the recognition that the exposure for residents living in the locality of sprayed fields is <u>high</u> has clearly been recognised in European legislation as residents (and <u>not</u> bystanders) are now specifically defined as a "vulnerable group" in Article 3, paragraph 14 of the European Regulation 1107/2009 which recognises that residents are "<u>subject to high pesticide exposure over the long term</u>."

As said, the UK Pesticides Campaign has continued to provide EFSA, the PPR Panel, as well as this Working Group, with visual materials to illustrate the factual reality of residents' exposure, and how it differs from the occasional exposure of a transient bystander, for example, the two videos on the DVD, and

a number of still photos. Prior to this technical hearing today I resubmitted 18 of these photos which hopefully all Working Group members will have received.

For the record of this hearing today I would like to point out the following.

One of the photos I resubmitted for WG members prior to this hearing is in relation to the exposure of transient *bystanders*, (as opposed to residents), and which shows a group of people walking along a public footpath, running through a field, and who are about to be met by a tractor spraying the field.

Four of the photos I resubmitted for Working Group members prior to this hearing were taken from the DVD I produced previously and show the sprayer passing right next to our garden on 3 separate spraying days over just a one month period in 2002 and passing right by (and almost over) the mannequin family I set out to illustrate the reality of where residents can be in their own garden. The mannequins were made up of some of the most vulnerable groups including a pregnant woman, 2 babies, and a young child, and they illustrated a typical and realistic residential setting, where people are out in their garden, and then with no warning, spraying takes place. As can be seen from the footage, the sprayer passes the mannequin family far closer than the 8 metres assumed in the existing risk assessment for bystanders (there is currently no risk assessment for the specific exposure scenario for residents), and it is also closer than the 2 metres that is proposed in the draft EFSA Guidance. This is the reality for many residents living in the locality of pesticide sprayed fields.

Two of the photos I resubmitted for Working Group members prior to this technical hearing are aerial pictures showing our house and garden on the boundary with one of the surrounding fields. Situated above the house (when viewing the picture) is the main part of our garden (as there is also garden over to the right as can be seen in the second of these aerial pictures and both sections of the garden have "Reflections" written on them in biro).

There were also two other aerial photos resubmitted of our house and that show the surrounding fields in our locality. On both these photos a small red circle marks our house, which is completely surrounded by fields that run for miles in all directions, which is obviously a common feature of many rural communities. (The scale of the first photo is approx. 1 mile left to right and the scale of the second photo is approx. 2 and a half miles left to right). These fields could be sprayed with different chemical mixtures on the same day, or on sequential days, on a regular basis, throughout every year, and have been for decades.

In the absence of being warned that hazardous chemicals were being used on fields in my locality, from the age of eleven, I was regularly in the garden when

crop-spraying was taking place, with the crop sprayer passing only a few feet away from me. As a result I suffered repeated acute exposures, along with repeated acute effects including sore throats covered in blisters, blisters/ulcers in the mouth (at times this could be as many as 20 at a time), headaches, dizziness, giddiness, and flu type illnesses. I have also suffered ongoing chronic exposures (as a result of living here for over 30 years), along with chronic effects, including diagnosed neurological damage/injury, and osteoporosis with a high risk of fracture, both of which have been confirmed as being as a result of exposure to pesticides sprayed in the locality of my home since 1984. (NB. I would also point out that in 2004 I had a number of pesticides found in blood and fat test results which confirmed the presence of pesticides in my system). Further, in addition to the chronic health problems I already have, I have been advised by a doctor that I have an increased risk of other chronic conditions developing, such as cancer, as a result of my long term exposure to pesticides.

Two of the photos I resubmitted for WG members prior to this technical hearing were additional photos of crop-spraying taking place right next to other residents' homes and gardens. In relation to the one with the reddish tractor coming right towards the resident's garden I would point out the following. This is the Robinson family who live in Suffolk. They actually have fields surrounding them on all sides. All members of the family that live there have suffered both repeated acute exposures, along with repeated acute effects such as burning eyes, sore throats, respiratory irritation, headaches, rashes, as well as ongoing chronic exposures (as a result of living there for over 38 years), along with chronic health effects, including the fact that 2 members of the family have diagnosed neurological conditions, and the other has long term damage to her eyes, and also has other long term chronic effects including sensitisation. All of their health problems have been linked to their exposure to pesticides sprayed.

The Robinson family have also documented over the years the extensive and clearly visible damage to plants and foliage in their garden which the HSE confirmed was from both spray drift and vapours from the spraying of the fields

Three of the photos I resubmitted for WG members prior to this technical hearing are of a resident's home and surrounding area on the Cambridge/Suffolk border. (The scale of the first photo is approx. 1 mile left to right; the scale of the second is approx. 2 and a half miles left to right, and the scale of the third is approx. 5 miles left to right). The small red circle marks the resident's house, which is again surrounded on all sides by fields that are regularly sprayed throughout every year. The crops are rotated regularly and there are often different crops in each of the 3 fields. All members of the household that live there have suffered both repeated acute exposures, along with repeated acute effects such as burning eyes, sore throats, coughs,

headaches, dizziness, rashes, blisters, as well as ongoing chronic exposures (as a result of living there for many decades), along with chronic health effects. These include the fact that 3 members of the family have neurological conditions, one has chronic asthma, nystagmus, and is in fact blind in one eye and has limited sight in the other eye. Another member of the household has had terminal lung cancer over a number of years and recently had a related brain tumour which has left him very ill and with a very short life expectancy. All of their health problems have been linked to their exposure to pesticides sprayed. It is also important to point out that the owner of the house and permanent resident there since 1968, Kay Wadey, was also exposed to pesticides sprayed on the surrounding fields during the times that she was pregnant with all of her four children. Her second child, Harry, was born prematurely with chronic damage to his lungs (which were not typical of the abnormalities seen in premature babies), and as a result he died when he was only 5 months old. Kay has informed me that one of the most recent spraying applications on 13th Sept. resulted in chemical fumes filling the house and Kay's 5 year old grandson commented on the "horrid smell" and wanted to get himself well away from it.

Two of the photos I resubmitted for WG members prior to this technical hearing show a resident's home within approx. 12 inches of a regularly sprayed field. The resident who sent me the photos said that whenever the surrounding field is sprayed it contaminates both the indoor and outdoor environment of their home.

Many of the 18 photos that I resubmitted for Working Group members prior to this technical hearing show that residents can be a metre or less away from a sprayed field. As said earlier, this is the reality for many residents living in the locality of pesticide sprayed fields, and who of course will not be involved in the pesticide application, and will not be wearing any protective equipment/clothing or overalls. There is currently no requirement in most Member States, if not all, for any sized zone to be left next to residents' properties and therefore a farmer is currently permitted to spray right up to a resident's home and garden if he/she so chooses and there is often no boundary structure between the sprayed field and the resident, home or garden (or school or playground). Indeed, as I have pointed out previously to EFSA, the PPR Panel, and this Working Group, even if there is a boundary structure, (eg. a fence, hedge etc.) this will not make any difference when it comes to pesticide droplets, particles or vapours in the air, as farmers cannot control pesticides once they are airborne (either at the time of application or subsequently) and therefore pesticides can travel over and above (or even through) such structures.

Another factual example to illustrate this can be seen in the short video clip I submitted for WG members prior to this technical hearing and which hopefully all Working Group members will have received. The video clip shows

pesticides being applied to crops right up to a resident's garden boundary. The chair situated in the resident's garden is right by where the sprayer passes and is again clearly within one metre away. The fence that can be seen in the video clip will not, as said earlier, make any difference when it comes to the exposure of the residents that live there to pesticide droplets, particles, and vapours, in the air, and indeed nor will it be able to prevent exposure to other exposure factors, such as exposure via contaminated surfaces both inside and outside their home.

The main reason that the distance between a sprayer and a person is being reduced from the existing 8 metres (which is currently used in the UK's bystander assessment) is to reflect the fact that <u>residents</u> and their homes and gardens are commonly, factually, and realistically, situated closer.

However, as said in both the UK Pesticides Campaign's summary and detailed comments on the EFSA draft Guidance, if it is based on 2 metres (which is what is proposed in the draft Guidance) then it is definitely not a "realistic worst case distance" as the many residents closer than 2 metres would not be accounted for in the proposed new exposure and risk assessment approach for residents. The distance recommended in the risk assessment **for residents** should be **1 metre.** 

The residents that live in the house related to the short video clip, Steven and Lorraine Duncan, are in the middle of fields, and therefore are surrounded on all sides. They have suffered repeated acute exposures, along with repeated acute effects such as burning eyes, lips, and nose. Steven says that he has these acute effects "every single time they spray without exception," and he says that the strong chemical fumes fill the air. They have also had ongoing chronic exposures (as a result of living there for over 14 years). Steven has developed a heart condition since he has lived there and says his health has deteriorated over the years. He always brings his 2 dogs and 2 cats in when the fields are sprayed having already lost one dog that died of a large cancerous tumour 2 years ago.

It is also important to note that Steven also pointed out that 3 residents in the area (from 2 of the 4 other houses) have developed Parkinson's disease since they have lived there. One of these residents subsequently died from the disease and her husband, a retired vicar, also now has the disease. They both lived in the same house, in the locality of pesticide sprayed crop fields, for many decades.

After a recent application of chemical pellets in the adjoining field (it is not clear whether the pellets were pesticides, fertiliser, or some other chemical), Steven found pellets all over his garden, including in his vegetable patch (where he tries to grow organic), and further, because he had the windows and doors open, the pellets were also all over the kitchen. When Steven challenged the farmer over the contamination of his home and garden he said that the farmer

simply replied along the lines of "It's very difficult to control it as it just comes out everywhere." Any WG member who has seen the 2<sup>nd</sup> video on the DVD will know that it contained a resident also reporting contamination of her property with hundreds of these chemical pellets which she described having to clear away to ensure her children did not pick them up and put them in their mouths.

The final two photos I resubmitted for WG members prior to this hearing were taken from the second video on the DVD that I produced previously to illustrate the real-life exposures, and acute and chronic adverse health impacts, of cropspraying on rural residents and communities. The two photos showed a woman indicating the close proximity of her children's school playground to one of the adjoining fields regularly sprayed, where the spray arm would come within a few feet of the place where the children attending the school would be playing.

Reports of ill-health effects suffered by a number of the children following pesticide spraying on the fields near to their school and playground included: skin rashes, eye irritation, sore throats, nausea, vomiting and flu-type illnesses.

As I highlighted in both the UK Pesticides Campaign's summary and detailed comments on the draft Guidance, the majority of pesticide data sheets are clear that acute effects, including both local and systemic, can occur from exposure.

It is important to note that the woman and her children also lived in the locality of pesticide sprayed fields which means her children were subjected to multiple exposure scenarios ie. where one individual's exposure takes place not only at home but also elsewhere – eg. at school, playground, office, or other buildings situated in the locality of pesticide sprayed fields. These are all **realistic** multiple exposure scenarios that **have not been accounted for** in the existing approach to exposure and risk assessment, which is again astonishing. It appears that this is not currently covered either in the proposed approach for residents exposure that is set out in the *draft* EFSA Guidance. Yet it is not uncommon for a child to live near sprayed fields <u>and</u> attend school near sprayed fields as well, which obviously increases the level of exposure to an even higher level.

In fact, as I have highlighted previously to EFSA, in my own case not only have I been repeatedly exposed to agricultural pesticides from living in the locality of crop fields for over 30 years, but for 5 years (between 11 and 16 years old) I also attended school in the locality of pesticide sprayed crop fields as well.

I would end the answer to this first question by reiterating again that a transient bystander occasionally exposed to pesticides <u>clearly does not have these types</u> <u>of exposure scenarios</u>. Therefore the differences between the exposure levels of these two separate resident and bystander groups again could not be clearer.

## <u>Question 2</u>: Could you please give factual examples of cases where the exposure of residents after a cycle of applications e.g. in cereals is higher than the operator's (or bystander's)?

The answer to question 1 above has already provided factual examples of cases where the exposure of residents is far higher than that of a transient bystander and this clearly includes after a cycle of applications on any given crop (ie. whether cereals, vegetable, or other crops). Bystanders will not be in the same place day after day and thus will only have occasional exposure if happening to walk past (or through) fields at the time a spraying application is taking place or thereafter. Further, it may be that a bystander will be able to limit his or her exposure to crop spraying (eg. by leaving the area etc.), but the same cannot be said of residents, who <u>live</u> in the area, in a fixed position, and clearly a house (or children's school or other building) cannot be moved from its fixed position.

As said earlier, residents living in the locality of sprayed fields are subjected to a combination of <u>both</u> repeated acute exposures and repeated chronic exposures, and cumulative exposures, <u>from a number of exposure sources</u> <u>and routes</u>, to innumerable mixtures of different pesticides sprayed on fields in the locality of residents' homes, over many years and in some cases, for decades. A bystander occasionally exposed to pesticides <u>clearly does not have</u> <u>this specific type of exposure scenario.</u>

The answer to question 1 above also provided factual examples of cases where the exposure of residents would be higher than that of an operator and this would again clearly include after a cycle of applications on any given crop, as in all the case examples referred to in answer to question 1, whilst the residents have had no protection from exposure (eg. no PPE, no filtered tractor cabs, lack of any access to information on the pesticides sprayed and prior notification etc.), the operators applying the pesticides in each of the factual examples provided will have had various personal protective measures at their disposal in order to reduce their exposure to a minimum whilst they are working with pesticides. (These include: the wearing of PPE, as well as the use of filtered cabs when applying pesticides, and having access to all the necessary chemical information, related warnings, material data sheets, of the pesticides to be used).

As I have pointed out previously to EFSA, the PPR Panel, and to this Working Group, the majority of reports over the years of acute toxicity in the UK Government's own monitoring system are for <u>residents</u>, rather than operators. This is not surprising considering that operators generally have protection and residents do not. Also in some cases pesticides are only approved on the basis of PPE reducing exposure for operators to within the AOEL which is not possible

for residents who will obviously not have any PPE, and of course, in any event, would not be expected to wear it on their own property and land.

As stated at footnote 4 of the UK Pesticides Campaign's detailed comments, the EFSA draft Guidance implies itself in places that the exposure without any PPE is many times higher than that with PPE. Considering residents have no PPE then for residents it is always a non-PPE scenario. It is therefore again clear that exposure of residents would be higher than that of an operator and this would again include after a cycle of applications on any given crop, (ie. whether cereals, vegetable, or other crops), considering the requirements for operators to be wearing PPE, as well as using filtered cabs, when working with pesticides.

# <u>Question 3</u>: Could you please provide exposure data on the worst case application condition for residents in UK (e.g. a house surrounded by 3 different crops, which crops and how many treatments per working season)?

Before actually responding to this question I think it is important for me to clarify from the outset that the exposure scenario that I have continued to highlight for residents (since 2001) is in relation to residents living in the locality of any pesticide sprayed field. Obviously when residents live in the locality of multiple fields, including when surrounded by fields on 3 or even 4 sides, it can increase exposure to pesticides even further, but it would be quite wrong and would miss the point entirely to suggest that a resident has to be surrounded on multiple sides, and by a particular pattern of crops, otherwise the exposure is not deemed to be significant because it is not considered to be a "worst case". That would be very seriously erroneous indeed. Crops can change not only year after year but throughout any one year (for example, if there are multiple crops in any one field in any one year etc.) Therefore residents will be receiving both acute and chronic exposures, over many years (and in many cases for decades), from a number of exposure sources and routes, to mixtures and combinations of different pesticides sprayed on any treated field in their locality, even if it is just one field. A resident is simply rightly defined as a resident (and in EU Regulations) if they live, work or attend a school or any other institution in the locality of a pesticide treated area.

Further, as will be seen in the following examples, in relation to the spraying <u>on</u> <u>any one field in any one year</u>, agricultural pesticides are rarely used individually, but are commonly sprayed in mixtures, and quite often a mixture in relation to any one application will consist of 4 or 5 different products mixed together. Each product formulation in itself can contain a number of different active ingredients, as well as other chemicals, such as solvents, surfactants and

other co-formulants (some of which can have adverse effects in their own right, even before considering any potential synergistic effects in a mixture(s)). Various studies have shown that mixtures of pesticides (and/or other chemicals) can have synergistic effects. Also, when 4 or 5 different products are sprayed in a mixture then this can realistically result in around 20 or so hazardous chemicals in any one application on any one field. Then when you multiply that up with the amount of spraying applications in any one field in any one year it is clear that residents will be exposed to innumerable mixtures and combinations of different pesticides sprayed on any one field in their locality (and this can be over many years and, in some cases, for decades) even before considering the exposure to innumerable mixtures and combinations of different pesticides sprayed throughout every year, for many years, on other crop fields in the area

It is absolutely clear that the <u>reality</u> of crop spraying in the countryside is <u>that there are innumerable mixtures of pesticides</u>, as well as other agricultural chemicals, being applied to crops, on a regular basis, year after year. In the UK, according to the UK regulators, there are, in fact, over <u>2,000 products</u> currently approved for use in agriculture, and further, approximately 80% of pesticides used in the UK each year are related to agricultural use.

In relation to residents living surrounded by multiple crop fields, I have already presented factual evidence to EFSA, the PPR Panel, and this Working Group that clearly show residents' homes surrounded on 3 or even 4 sides by fields that run for miles in all directions, which is obviously a common feature of many rural communities. This can clearly be seen from a number of the 18 photos that I resubmitted for Working Group members prior to this technical hearing, as well a number of the case examples contained on the two videos on the DVD previously provided to EFSA, the PPR Panel, as well as this Working Group. The answer to question 1 above also included some factual examples of cases where residents' homes are surrounded on all sides by crop fields that are regularly sprayed throughout every year, and that have been for many decades.

In relation to the crops that have the highest number of spraying applications here in the UK I would highlight the following few examples using the latest and most up to date figures from the UK Government's Pesticide Usage Survey.

However, I would stress the fact that all the following figures are <u>average</u> <u>figures</u>, and therefore it does not necessarily mean that there won't be more spraying applications or more products used on any given crop. Also please note that some of the figures won't necessarily match (if simply adding them up) due to the fact that multiple products are often used together in a tanx mix.

(NB. I would also stress the fact that the following examples are in relation to the UK <u>only</u> (as the question asked), and data on crops and applications may be different in other European countries, (as there are obviously vast areas of crop fields not only here in the UK but in other Member States across Europe)).

For orchards the crop with the highest number of spraying applications according to the UK Government's Pesticide Usage Survey 2012 data is apples, as both cox's apples and desert apples have 21 spraying applications on average per working season. Considering the breakdown of these spraying applications is similar for both then I will just go through the one related to cox's apples.

The 21 spraying applications consists of 17 fungicide applications, involving 32 products. Fungicide applications usually use multiple products mixed together in a tanx mix, with 2 products on average per mix. This is why the number of products regarding fungicides is higher than the number of spraying applications, and they are also often applied mixed with insecticides as well.

I would point out that these fungicide applications include 3 applications on average of dithianon, which is often tank mixed with other pesticides. (NB. As I have already previously detailed in a number of written submissions sent to EFSA, the PPR Panel, and this Working Group, in July 2003 the UK regulators (to be precise Paul Hamey from PSD (now CRD)) found 82 exceedances of the EU limits set for exposure (the AOEL), when considering a few additional limited exposure sources for residents, and in some cases the AOEL was exceeded up to 20 to 30 times over, which is an order of magnitude higher. In one case, in relation to exposure to dithianon (in Dithianon Flowable), exposure at 8 metres from the sprayer (ie. under the existing UK bystander exposure assessment) exceeded the AOEL up to thirty-one and a half times over. Further, based on the UK regulators own figures there would have been an exceedance of 95 times above the AOEL at 3 metres from the sprayer and which would have been well over 100 times over at 1 metre from the sprayer. As I have already demonstrated in various visual materials and factual case examples provided to EFSA, the PPR Panel, and to this Working Group, some residents homes and gardens are a metre or less away from where a sprayer passes. Under EU law any exceedance of the AOEL (even just by 1 time over) is supposed to lead to immediate action of authorizations being refused, or trigger prohibition/revocation if the exceedance is discovered after approval. Yet products containing Dithianon still remain approved for use in the UK, including Dithianon Flowable which is approved until 2021, for use on apples and pears. See paras 20(e), 23(b), 28, 32 to 36 and footnote 39 of the second Witness Statement I produced for the legal case).

The 21 spraying applications on average per working season regarding cox's apples also consists of 5 insecticide applications (involving 5 products) – and as said earlier, insecticides are usually applied tank mixed with fungicides; 2 herbicide applications (involving 3 products) – herbicide applications usually use multiple products mixed together in a tanx mix; and 6 growth regulators which are also pesticides (involving 7 products).

For arable the crop with the highest number of spraying applications according to the UK Government's Pesticide Usage Survey 2012 data is ware potatoes that have 15 spraying applications on average per working season which is from around April/May when they are planted to September/October when lifted.

The 15 spraying applications consists of 11 fungicide applications, involving 5 products, (fungicide applications usually use multiple products mixed together in a tanx mix); 1 insecticide application (involving 1 product); 3 herbicide applications (involving 4 products); as well as 1 molluscicide application.

It is important to note that unlike with apples for ware potatoes there may well be double cropping in some cases if an earlier potato has gone in around March. I have been informed by the UK's Pesticides Usage Survey that more often though, for potatoes, there may be double cropping with some vegetable crops, and so, as said earlier, residents living in the locality can be exposed to *even further* spraying applications when there are **multiple crops in any one field in any one year**.

At paragraph 1.18 of the UK Pesticides Campaign's detailed comments on the EFSA draft Guidance I pointed out the fact that spraying in any one year is often for longer than a "working season" of 3 months, and can indeed go on for a whole year if a crop is planted through the winter in addition to the crop(s) grown earlier in that year. A related point to this is the fact that whilst some crops (eg. salad onions) may have a smaller number of spraying applications per crop grown (although it should be noted that less spraying applications can sometimes be as a result of more pesticide products being used together in a tank mix), there will often be double cropping of that crop and so again the number of spraying applications would obviously be increased in any one field in any one year when there are multiple crops of that particular crop, and/or another crop, in a field in the locality of residents homes, schools, children's playgrounds, nurseries etc. Also that is obviously before including the repeated applications on any other crop fields that are also in the locality of those same residents homes, schools, children's playgrounds, nurseries etc.

For vegetable crops the crops with the highest number of spraying applications according to the UK's Pesticides Usage Survey 2013 data is dry bulb onions

and leeks that have 11 spraying applications each on average per working season. The 11 spraying applications consists of 5 fungicide applications, involving 8 products, (fungicide applications usually use multiple products mixed together in a tanx mix); 2 insecticide applications, involving 2 products, (insecticides are usually applied tank mixed with fungicides); and 6 herbicide applications, involving 13 products. Herbicide applications usually use multiple products mixed together in a tanx mix and so again this is why the number of herbicide products is higher than the number of herbicide spraying applications.

I would stress again the fact that all these figures are <u>average figures</u> as the UK Pesticide Usage Survey data points out the fact that some of these crops (eg. cox apple, ware potato, and dry bulb onion and leek), or indeed in relation to other crops, will be receiving a higher number of pesticide applications than the average figures for various reasons including, for example, differences in the length of their growing season, pest, disease and weed pressure etc. Therefore as said earlier, the average figures recorded will not necessarily mean that there won't be more spraying applications or more products used on any given crop.

It is also important to note that in addition to all the aforementioned pesticide applications (ie. with insecticides, fungicides, herbicides, growth regulators), there will also usually be applications of other agricultural chemicals and products as well (and that may lead to some resulting exposure for residents in the locality), for eg., acaricides (another pesticide category), adjuvants (which are in addition to any adjuvants that may be present in any of the pesticide products used), urea, chemical fertilisers, sulphur, amongst others.

Therefore if going by the Working Group question then a "worst case" application condition for residents in the UK based on these examples would be residents that are surrounded by any of these crops on all sides. However, as said at the outset of this question it would be quite wrong and would miss the point entirely to suggest that a resident has to be surrounded on multiple sides, and by a particular pattern of crops, otherwise the exposure is not deemed to be significant because it is not considered to be a "worst case". That would be very seriously erroneous indeed as residents will be receiving both acute and chronic exposures, over many years (and in many cases for decades), from a number of exposure sources and routes, to mixtures and combinations of different pesticides, sprayed on any field in their locality, even if it is just one.

I would highlight the following factual case example in relation to the exposure and adverse health impacts on residents living in the locality of just one pesticide sprayed field. Keren Robbins was subjected to years of pesticide spraying in the locality of her home, while suffering from both a neurological condition, and Multiple Chemical Sensitivity (MCS). There was one large field in her direct locality which was at the time being used for growing potatoes. Keren was left feeling so powerless to stop the chemical onslaught that, after a spraying application in 2009 in which she suffered further adverse effects on her health, she took her own life by jumping in front of a train. Her husband was left utterly devastated at the loss of his wife. The records I have of the phone conversations I had with Keren before her tragic passing clearly show that she reported that there were a number of spraying applications per week over a number of weeks in the field with the potatoes. As said, this is in relation to the spraying on just one field in the locality of Keren's home and from which she was exposed over many years, to mixtures and combinations of different pesticides sprayed on that field.

It is also important to highlight that for any residents living in the locality of any crop sprayed fields it can be a "worst case" scenario because of other specific factors involved. For example, the campaign I run has received many reports of people being poisoned from crop spraying in the locality of their homes and many involve children. I would highlight the following factual case as an example. I was previously contacted by a resident whose family includes 2 year old twin girls, and in total there are 6 children under the age of 14. The whole family have suffered repeated ill-health following the spraying of crop fields in the locality of where they live - they are within 3 metres away from the nearest field. For example, they have all suffered from repeated nose bleeds, which is known to be an acute adverse effect of pesticide exposure. And the twins have had chesty coughs, raspy breathing and cold/flu like symptoms at certain times. The resident informed me that their local GP has confirmed that pesticide spraying is the most likely cause of their symptoms. He himself has also suffered from neurological symptoms which he describes as being similar to those of Multiple Sclerosis. Also a few years ago his dog developed lymphoma.

Therefore *any* case should be considered a "worst case", as <u>no</u> residents (including babies and young children, as well as other vulnerable groups such as pregnant women, the elderly, those who are already ill or disabled) should have <u>ever</u> been exposed to these chemicals in the first place, as under EU law <u>no</u> pesticides should have been approved in the absence of any actual risk assessment specifically for residents exposed from crop spraying in the locality of their homes, as well as schools, playgrounds, etc.

<u>Question 4</u>: Could you please provide data identifying the amount and the ranking of resident exposure to pesticides in "particles, droplets, vapours in the air in the days, weeks and months after applications;... in precipitation

and via reactivation, pollen, dust (including harvest dust), soil; pesticides transported from outdoor application and redistributed into an indoor air environment; exposure via long-range transportation"

I did not have enough time to prepare a response to this question in the few days I had to prepare, as I have only been able to carry out limited work recently due to health problems. Therefore considering the detailed responses to questions 1 and 3 in particular, I was not able to consider this question in any capacity in the time left. However, having said that, as far as I am concerned this question has definitely already been answered in the factual evidence and materials already submitted to EFSA, the PPR Panel, and this Working Group, since 2006, in particular in the second Witness Statement produced for the legal case *Georgina Downs v DEFRA* (especially, although not only, in great detail at paragraph 56), as well as in the UK Pesticides Campaign's detailed comments submitted on the EFSA draft Guidance (especially, although not only, at paragraph 1.65).

This includes in relation to highlighting reputable international studies that have reported on some of these specific exposure factors, (and which I cited from extensively in the aforementioned factual evidence referred to). I can send in any references to where these were in due course, if required, but they included:

Bedos et al, "Mass transfer of pesticides into the atmosphere by volatilisation from soils and plants: overview", Agronomie 22 (2002) 21-33.

Bedos et al, "Occurrence of pesticides in the atmosphere in France."

Lee et al, "Community Exposures to Airborne Agricultural Pesticides in California: Ranking of Inhalation Risks" (2002).

Lu et al, "Pesticide exposure of children in an agricultural community: evidence of household proximity to farmland and take home exposure pathways."

Cornell University's publication "Toxicity of Pesticides."

Bell *et al*, 2001 study that involved nearly 700 Californian women showed that living **within a mile** of farms where certain pesticides are sprayed, during critical weeks in pregnancy, increased by up to 120% the chance of losing the baby through birth defects.

Sadie Costello, Myles Cockburn, Jeff Bronstein, Xinbo Zhang, Beate Ritz 2009 study that I have previously highlighted to EFSA, PPR Panel, and the Working Group, that found that exposure to just two pesticides within 500 metres of residents' homes increased the risk of Parkinson's Disease by 75%.

Alarcon et al, 2005 study "Acute Illnesses Associated with Pesticide Exposure at Schools" that confirmed acute illnesses in children and employees from pesticides sprayed on farmland in the locality of schools, and that pointed out that, at the time the study was prepared, a number of US states required the prohibition of spraying in the locality of schools in an attempt to protect children from exposure, including one state where the distance of the area where the use of pesticides was prohibited in locality of schools was 2.5 miles.

Therefore I would just refer back to all that I have submitted previously considering I have not had time to prepare anything in response to this question.

Incidentally, in relation to the part of question 4 regarding the ranking of resident exposure to pesticides in relation to those specific exposure factors/sources, as anyone who has read the factual evidence that the campaign I run has submitted over the years will see, I would not necessarily rank them in any event, as they <u>all</u> have to be included in the exposure calculations for a residents specific exposure scenario *irrespective* as to whether some are lower than others and this leads me onto the response to question 5 of the questions....

## <u>Question 5</u>: Based on the data provided under point 4, could you please propose which of these factors should be taken into account (or prioritised) in a model?

As I highlighted in both the UK Pesticides Campaign's summary and detailed comments on the EFSA draft Guidance, as well as in numerous other previous submissions provided to EFSA, the PPR Panel, and to this Working Group, all these exposure factors, amongst others, are relevant to a residents specific exposure scenario as it is about the overall exposure that residents and communities are receiving in totality (regardless as to whether some exposures are lower than others). It is therefore clear that any new exposure and risk assessment model for residents would need to include all the relevant exposure factors, and routes (inhalation, dermal, oral and eyes etc.), including in relation to both the acute exposures, and chronic longer term exposures, as a resident can realistically receive high acute exposures at any time spraying occurs (as well as the long term exposures they will receive over years, even decades). All the exposure factors and exposure routes would need to be included in the exposure calculations and then added together (summed) for the assessment of the overall exposure in totality, as no exposure assessment and resulting risk assessment for any exposure group can be adequate or complete if some of the exposures are ignored in the exposure calculations.

Considering that in a <u>realistic</u> residents exposure scenario, residents will be exposed to <u>mixtures</u> and combinations of pesticides over the long term, then the exposure assessment and resulting risk assessment for residents just referred to cannot be based on each pesticide considered <u>individually</u>, as it is clearly inherently flawed to merely calculate exposure to each pesticide in <u>isolation</u> and therefore for a residents exposure scenario the exposure calculations have to include all these exposures factors, amongst others, and all routes, <u>in</u> relation to the <u>mixtures of pesticides residents are exposed to</u>, from multiple applications (including on the same field, as well as sequential/repeated applications on other fields in the locality), over the long term, (and this would clearly have to include all the cumulative exposures, and synergistic effects etc.)

As I highlighted in paragraph 1.136 of the UK Pesticides Campaign's detailed comments on the EFSA draft Guidance, based on the results shown in the UK regulators (PSD now CRD) own findings in 2003, residents can be subjected to multiple exposures exceeding the AOEL (and in many cases at an *order of magnitude higher*), *even before* factoring in any other active ingredients that also exceed the AOEL within the same product, and/or in other products applied at the same time, and/or applied over the course of the growing season, and then applied year after year, and even realistically (for those living near any fields) over many decades.

And further still it is <u>before</u> factoring in all the other chemicals in all the various product formulations being applied, over the long term, such as solvents, surfactants and other co-formulants (some of which can have adverse effects in their own right, even before considering any synergistic effects in a mixture(s)).

The fact that, to date, there has never been <u>any</u> assessment of the risks to health for this type of realistic exposure scenario for residents who live in the locality of sprayed fields, as well as those who go to school and/or attend playgrounds in the locality of sprayed fields, means that under EU law pesticides should <u>never</u> have been approved for use in the first place for spraying in the locality of residents' homes, schools, playgrounds, amongst other areas.

In fact, as I highlighted in paragraph 1.156 of the UK Pesticides Campaign's detailed comments on the EFSA draft Guidance, it is absolutely clear that if a proper and full assessment were to be undertaken to assess the exposure and risk for residents (that would have to include in the exposure calculations <u>all</u> the exposure factors and routes, both higher and lower levels of exposure, and to mixtures of different pesticides over the long term and then added together), then the result would be that pesticides would simply <u>not</u> be allowed to be approved <u>at all</u> for use in the locality of residents' homes, as well as schools, children's playgrounds, nurseries, amongst other areas.

#### **Concluding comments**

To date there has been <u>no protection</u> for residents and communities from exposure to pesticides sprayed on crops, the inherent health risks, and related acute and chronic adverse health impacts. Rural citizens across Europe have been put in a massive guinea pig-style experiment and for which many of us residents have had to suffer the serious and devastating consequences of.

The principal aim of pesticide policy, under EU law, is clearly based on the <u>risk</u> of harm, and <u>not</u> that harm has to have already occurred. Therefore as I have continued to correctly argue throughout the campaign, under EU law residents are <u>not</u> supposed to be exposed to the risk of harm to their health (whether in relation to acute or chronic effects) from exposure to pesticides.

As said at para 1.155 of the UK Pesticides Campaign's detailed comments, farmers cannot control pesticides once they are airborne and therefore exposure for residents is not about the misuse, abuse or illegal use of pesticides, but about the permitted, approved use of these substances.

EFSA, with its public health remit, should be advising the EU political institutions to take urgent action on this issue to introduce the necessary measures for the protection of the health of rural residents and communities across Europe. Such measures would include the prohibition of the use of pesticides in **substantial distances** (as small buffer zones won't be protecting anyone!) in the locality of residents' homes, schools, playgrounds, nurseries etc. This is absolutely crucial for public health protection as pesticides should *never* have been approved for use for spraying in the locality of any of these areas.

If any Working Group members have not already seen it I would strongly urge you to watch the two videos on the DVD that were produced to illustrate the <u>reality</u> of crop spraying in the locality of residents homes, as well as in the locality of schools, children's playgrounds etc. The second video on the DVD featured, just as an example, a few of the individuals and families from all over the country reporting acute and/or chronic adverse health effects in rural communities surrounded by fields that are sprayed with pesticides. It is important to stress that obviously there are many, many more cases than the few examples that are on the DVD, as well as those that I have highlighted in the responses to the various questions asked by the WG.

If Working Group members require anything further please let me know.

Georgina Downs, FRSA, IFAJ, BGAJ. UK Pesticides Campaign



## EFSA Pesticides Unit Minutes of the 6<sup>th</sup> meeting of the EFSA Working Group on Operator, Worker, Resident and Bystander Exposure Guidance

Parma, 10-12 09 2014 (Agreed on 30 09 2014)

#### **Participants**

- Working Group Experts:
  - Claudia Grosskopf
  - Paul Hamey
  - Sabine Martin
- European Commission and/or Member States representatives:
  - none
- EFSA:
  - Pesticides Unit:
     Manuela Tiramani (Chair of the WG)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Kiki Machera and Walter Steurbaut

#### 2. Adoption of agenda

The agenda was adopted.



#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest (ADol) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Discussion of the comments received during the public consultation of the draft Guidance Document and calculator

The comments received during the public consultation were discussed as well as the draft answers prepared by EFSA.

#### 5. Discussion of the amendments to the draft guidance and calculator

Based on the outcomes of point 4 of the agenda, the draft Guidance was revised accordingly. The calculator will be revised after the final check and agreement on the Guidance.

#### 6. Any other business

The next steps of the activity were illustrated by EFSA, as well as correlated activities (e.g. technical hearing).

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



#### **EFSA Pesticides Unit**

#### Minutes of the 5<sup>th</sup> meeting of the EFSA Working Group on Operator, Worker, Bystander and Residents Exposure Guidance

TELE-conference, 13 02 2014 (Agreed on 26 02 2014)

#### **Participants**

- External Experts:
  - Claudia Grosskopf
  - Paul Hamey
  - Sabine Martin
  - Walter Steurbaut

#### • EFSA:

- Pesticides Unit: Manuela Tiramani (Chair), Hans Steinkellner
- Assessment and Methodological Support Unit: Jane Richardson

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Kiki Makera.

#### 2. Adoption of agenda

The agenda was adopted without changes.



#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

## 4. Agreement of the minutes of the 4<sup>th</sup> Working Group meeting held on 26-27 Sept 2013, Parma

The minutes were agreed on 25 October 2013 and published on the EFSA website on 30 October 2013.

#### 5. Scientific topics for discussion

The updated version of the Guidance was discussed.

In particular, the following points were considered:

- Consideration of other existing initiatives in the field of exposure assessment (e.g. BROWSE)
- Default parameters proposed (e.g. body weight, whole working day inhalation rate, surface areas)
- A final check of the available data for the operator exposure assessment for different scenarios was performed
- A final check of the available data and appropriateness of the different personal protective equipments was performed
- A final check of the available data for the transfer coefficient to be used for the worker exposure was performed
- All the key parameters to be used for the resident and bystander exposure assessment were considered and checked. Some follow-up is needed after the TC

#### 6. Next steps

EFSA will revise the draft Guidance (to reflect the discussion held with the experts) and the draft calculator (which will include new and/or revised data, according to the expert discussion).

A revised draft of both guidance and calculator will be circulated to the experts within the end of Feb. After a final check, a public consultation will be launched in the first half of March for at least 6 weeks.

<sup>1</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



## Pesticides Unit Minutes of the 4<sup>th</sup> meeting of the EFSA Working Group on

Operator, Bystander, Worker and Resident Exposure Guidance Held on 26-27 09 2013, Parma

(Agreed on 25 10 2013)

#### **Participants**

- Working Group Experts:
  - Claudia Grosskopf
  - Paul Hamey
  - Sabine Martin
  - Walter Steurbaut
- EFSA:
  - Jane Richardson, Hans Steinkellner (on 26 Sep), Manuela Tiramani (Chair)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Kyriaki Machera.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the

<sup>1</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

## 4. Agreement of the minutes of the 3<sup>rd</sup> Working Group meeting held on 24 September 2012 by TELE-conference.

The minutes were agreed by written procedure on 19 October 2012 and published on the EFSA website 24 October 2012.

#### 5. Scientific topics for discussion

#### 5.1 EFSA Guidance Document (EFSA-Q-2011-01062)

After the mandate received from COM requesting EFSA to consider the possible inclusion of the new data used to developed the AOEM model (BfR 2012), a meeting of the Working Group is organised to discuss a revised draft guidance containing some of the comments received during the consultation COM did with MSs (ended in Feb 2013) and a revised calculator including the new AOEM data, to discuss their appropriateness for the EFSA Guidance.

The WG agrees to include the AOEM data, which will replace the existing old data on the same scenarios; where relevant, the comments from the first consultation run by COM with MSs were considered and addressed.

#### 5.2 Next steps

EFSA will revise the draft Guidance (to reflect the discussion held with the experts) and the draft calculator (which will include new and revised data, according to the expert discussion).

A revised draft of both guidance and calculator will be circulated to the experts by mid December and comments will be collected end of January. If necessary, both documents will be revised and a public consultation will be run by EFSA for at least 6 weeks.

#### 6. Next meeting

To be decided



Parma, 22 October 2012

#### **Minutes**

#### 3<sup>rd</sup> Meeting of the EFSA Working Group on Operator, Worker, Bystander and Residents Exposure Guidance

(Agreed in a written procedure on 19<sup>th</sup> October 2012)

Date:	24 <sup>th</sup> September 2012
Time:	9:30 – 13:00 CET
Place:	TC

#### Participants:

EFSA: Jane Richardson, Manuela Tiramani (Chair)

External experts: Paul Hamey, Sabine Martin, Walter Steurbaut, Kiki Machera

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Lena Jacobi and Hans Steinkellner.

#### 2. Adoption of agenda

The agenda was agreed.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

#### 4. Discussion about the updated version of the calculator

A list of unresolved issues for teleconference / expected input from experts was discussed.

The experts discussed the issues. EFSA staff will update the the calculator accordingly. The WG agreed to sort out the issue and will try to do that by end of September (constituting a factual delay in the work of about 2 weeks).



#### 5. Discussion about the updated draft guidance

An updated version of the draft guidance was presented. The experts then discussed the new draft and all outstanding issues. An updated version will be sent out after the meeting containing all agreed amendments.

6. Further activities until calculator will be submitted to Commission for a trial phase

To test the calculator and its compliance to the guidance document.

Hans Steinkellner



Parma, 5<sup>th</sup> October 2012

#### **Minutes**

#### 2<sup>nd</sup> Meeting of the EFSA Working Group on Operator, Worker, Bystander and Residents Exposure Guidance

(Agreed in a written procedure on 21<sup>st</sup> September)

Date:	6 <sup>th</sup> – 7 <sup>th</sup> September 2012
Time:	14:00 - 18.00 and 9:00 - 13:00 CET
Place:	Meeting Room M 05, EFSA, Via Carlo Magno 1a, 43126 Parma

Participants:

EFSA: Lena Jacobi, Jane Richardson, Manuela Tiramani, Hans

Steinkellner (Chair)

External experts: Paul Hamey, Sabine Martin, Walter Steurbaut

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Kiki Machera.

#### 2. Adoption of agenda

A revised agenda containing was distributed at the meeting and agreed by the participants.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

#### 4. Discussion about the updated version of the calculator

A presentation was given about the updated calculator which contained also questions on specific issues/scenarios.



The experts discussed the issues. The calculator will be updated accordingly. Discussion about the updated draft guidance

An updated version of the draft guidance was presented and discussed. An updated version will be sent out after the meeting containing all agreed amendments.

#### 5. Discussion about additional data

The relevance of the additional data that were posted on the extranet already in August was discussed by the experts.

## 6. Further activities until calculator will be submitted to Commission for a trial phase

It was agreed that it was aimed at sending the draft guidance and the calculator to the Commission by end of September.

### 7. Drafting of recommendations for Commission for the trial phase – which substances and which scenarios should be tested

The issue was discussed. Participants were asked to provide further ideas in the follow-up period of the meeting.

#### 8. Next meetings

Teleconference, 24th September, 9.30 - 13.00 CET

9. Any other business



Parma, 1<sup>st</sup> August 2012

#### **Minutes**

#### 1<sup>st</sup> Meeting of the EFSA Working Group on Operator, Worker, Bystander and Residents Exposure Guidance

(Agreed on 27<sup>th</sup> July 2012)

Date:	9 <sup>th</sup> – 10 <sup>th</sup> July 2012
Time:	14:00 - 18.00 and 9:00 - 13:00 CET
Place:	Meeting Room M05, EFSA, Via Carlo Magno 1a, 43126 Parma

Participants:

EFSA: Lena Jacobi, Jane Richardson, Manuela Tiramani, Hans

Steinkellner (Chair)

External experts: Kyriaki Machera, Paul Hamey, Sabine Martin, Walter Steurbaut

#### 1. Welcome and apologies

The Chair welcomed the participants. No apologies were received.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

#### 4. Presentation and discussion of scope and timeline for the mandate

Scope and timeline of the mandate was presented and briefly discussed by the WG.



### 5. Presentation and discussion on progress on checking of values and work on the calculator and outstanding issues

Progress in checking of values to be applied for different exposure models and a first version of a future exposure calculator were presented. The features of the calculator were discussed by the WG. Further activities needed for finalisation of the calculator were agreed upon.

#### 6. Presentation on possible inclusion of additional data

An overview about the data available/not available for finalisation of the guidance was given.

## 7. Presentation of proposals for changes and amendments to the draft guidance and discussion

An updated draft guidance considering the recommendations given by the Commission was presented by EFSA and was then discussed by the WG. Further amendments to the draft guidance were made by the WG.

#### 8. Discussion about work plan, time line and allocation of tasks to WG members

A work plan was discussed and agreed upon. Specific tasks were allocated to different WG members.

#### 9. Next meetings

6 (p.m.) - 7 (a.m.) September 2012, EFSA, Parma

10. Any other business

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