# TOXICITY AND HUMAN HEALTH RISKS ASSOCIATED WITH MONSANTO'S ROUNDUP AND OTHER GLYPHOSATE BASED HERBICIDES (GBH) RESIDUES IN OUR FOOD AND WATER.





The Joint WHO-FAO Meeting on Pesticide Residues (JMPR) - the arm of the WHO that determines and sets the so-called "safe" level of pesticide residues allowed in our food, water, etc, - has declared that glyphosate/Roundup is unlikely to cause cancer through pesticide residues in our food [1]

Monsanto and regulatory agencies in the US (EPA), EU (EFSA) and in Canada (Health Canada) are attempting to discredit and to dismiss the recent WHO/International Agency for Research on Cancer (IARC) credible and alarming classification of glyphosate as a "probable human carcinogen" by arguing that a health hazard is not a health risk because - they erroneously argue - a health risk is based on the level of human exposure to glyphosate/Roundup.

# GLYPHOSATE, ROUNDUP: ENDOCRINE DISRUPTING CHEMICALS (EDC) TOXIC AT LOW/MINUTE DOSES:

However, both glyphosate, Roundup and each one of its so-called "inert" and "secret" coformulants have alarmingly been found to be endocrine disrupting chemicals (EDCs) which are extremely toxic to human health at low/minute doses.

As the following paper explains:

"The endocrine disrupting effect of glyphosate and its commercial formulations (i.e. Roundup) is their most insidious and worrying toxic effect. This is because EDC's do not function like normal poisons, where a higher dose gives greater toxicity. Often, endocrine disruptive effects are seen at lower doses but not at higher doses. The studies conducted by industry for regulatory purposes use relatively high doses and are not able to detect these effects.

Endocrine disruption in humans is thought to contribute to some cancers, birth defects, reproductive problems such as infertility, and developmental problems in foetuses, babies, and children.

Under European law, pesticides that disrupt hormones ("endocrine disrupting chemicals" or EDCs) are not allowed to be marketed. Governments recognize the threat posed by endocrine disruption, which are believed to be implicated in serious diseases, such as cancer, reproductive and developmental problems, and birth defects. These effects are thought to result from very low doses over a long period of exposure or from exposures in critical windows of development, such as foetal development in the womb." [2]

Alarmingly, professor <u>Gilles-Éric Séralini</u> and his team of prominent and eminent researchers have recently found both glyphosate, Roundup as well as their so-called "inert" co-formulants to be endocrine disrupting chemicals (EDC). In their landmark published research paper [3], Seralini et al. write:

#### Excerpts:

"A new study shows that the acceptable daily intake (ADI), the supposedly safe level, for glyphosate is unreliable in terms of assessing the risks of the complete commercial formulations that we are actually exposed to. The co-formulants were shown in the new study to have a far more powerful endocrine-disrupting effect at lower doses than the isolated active ingredient, glyphosate. The complete formulations (i.e Roundup) were also found to have much greater endocrine disrupting effects at lower doses than glyphosate alone. The research shows that the ADI should be calculated from toxicity tests on the commercial formulations as sold and used. The new study is the first ever demonstration that the endocrine disrupting effects of glyphosate based herbicides (GBH) are not only attributable to glyphosate, the declared active ingredient, but above all to the co-formulants."

# As the following paper further explains:

"The so-called "safe" levels of glyphosate exposure have never been tested directly to determine if indeed they are really safe to consume over the long term. Instead the "safe" levels are extrapolated from higher doses tested in industry studies. Industry toxicity study protocols are out of date. All toxicity tests conducted by industry for regulatory purposes are based on the old adage: "The dose makes the poison" – that is, the higher the dose, the greater the degree of toxicity. However, in some cases, low doses corresponding to human exposures can be more toxic than the higher doses tested in laboratory animals in industry studies.

This is especially true for chemicals that disrupt the hormonal system (endocrine disruptors). Safe levels of these chemicals cannot be extrapolated from effects at higher doses. Evidence from in vitro and animal experiments shows that glyphosate may be an endocrine disruptor at levels permitted in tap water in the EU. Findings that glyphosate and its commercial formulations may be endocrine disruptors imply that the standard industry long-term animal studies are inadequate. These studies are conducted on adult animals, and fail to test the effects of exposure during important windows of development, such as foetal development. Yet hormones are vital regulators of development. A subtle hormonal effect during early life can modify organ morphology and function for the rest of the life, as well as potentially leading to chronic diseases such as cancer and reproductive dysfunction in adults.

The complete glyphosate herbicide formulations as sold and used contain additives (adjuvants), which are toxic in their own right and/or increase the toxicity of glyphosate. Safety limits are set for the isolated ingredient glyphosate, but the whole formulations, which are generally more toxic, are never tested to determine long-term toxic effects. This limitation of the regulatory process applies to all pesticides in all countries worldwide. Studies in rats confirm that the complete glyphosate herbicide formulations are toxic at levels deemed safe by regulators for the isolated ingredient glyphosate. Other feeding studies in pigs and rats directly comparing the toxicity of formulations with glyphosate alone found that the formulations were far more toxic.

Even glyphosate alone may not be as safe as claimed. Industry tests on glyphosate alone revealed toxic effects, notably birth defects, below the levels that regulators claimed showed no toxic effect – but these results were ignored or dismissed by regulators in setting the supposedly safe ADI. Independent studies have found toxic effects of glyphosate and its commercial formulations at environmentally realistic levels, which have never been tested by regulators. Effects include oxidative stress on liver and kidneys and endocrine disrupting effects. These findings, taken as a whole, suggest that the levels of Roundup we are exposed to may not be safe over the long term." [4]

The following studies [5] have also found both glyphosate and Roundup to be EDCs.

Moreover, a Scientific Consensus Statement [6] recently published by a number of prominent and eminent scientists states:

#### Abstract:

"Our Statement of Concern considers current published literature describing glyphosate based herbicides (GBH) uses, mechanisms of action, toxicity in laboratory animals, and epidemiological studies. It also examines the derivation of current human safety standards.

We conclude that: (1) GBHs are the most heavily applied herbicide in the world and usage continues to rise; (2) Worldwide, GBHs often contaminate drinking water sources, precipitation, and air, especially in agricultural regions; (3) The half-life of glyphosate in water and soil is longer than previously recognized; (4) Glyphosate and its metabolites are widely present in the global soybean supply; (5) Human exposures to GBHs are rising; (6) Glyphosate is now authoritatively classified as a probable human carcinogen; (7) Regulatory estimates of tolerable daily intakes for glyphosate in the United States and European Union are based on outdated science. (emphasis is mine)

We offer a series of recommendations related to the need for new investments in epidemiological studies, biomonitoring, and toxicology studies that draw on the principles of endocrinology to determine whether the effects of GBHs are due to endocrine disrupting activities. We suggest that common commercial formulations of GBHs should be prioritized for inclusion in government-led toxicology testing programs such as the U.S. National Toxicology Program, as well as for biomonitoring as conducted by the U.S. Centers for Disease Control and Prevention."

The <u>Endocrine Society</u> has also recently published an alarming (2nd) Scientific Statement [7] on the toxicity of EDC's:

### Excerpts:

"This Executive Summary to the Endocrine Society's second Scientific Statement on environmental endocrine-disrupting chemicals (EDCs) provides a synthesis of the key points of the complete statement. The full Scientific Statement represents a comprehensive review of the literature (1300 studies) on seven topics for which there is strong mechanistic, experimental, animal, and epidemiological evidence for endocrine disruption, namely: obesity and diabetes, female reproduction, male reproduction, hormone-sensitive cancers in females, prostate cancer, thyroid, and neurodevelopment and neuroendocrine systems. Scientific advances over the past 5 years (encompassing 1300 studies) reveal numerous EDC effects on obesity, diabetes, male and female reproduction (including cancer), the prostate and thyroid glands, and neurodevelopment. The past 5 years represent a leap forward in our understanding of EDC actions on endocrine health and disease."

#### Glyphosate/Roundup: Risk Assessment: Health Hazard vs Health Risk

Furthermore, the risk assessment of glyphosate/Roundup and GBHs carried out by regulatory agencies is scientifically flawed for the reasons briefly explained below.

## 1) "The dose makes the poison"

The health hazards vs health risks assessment used by all regulatory agencies is scientifically outdated and flawed because regulators erroneously believe the 500 year old adage that the "dose makes the poison." However, recent toxicology peer-reviewed and published scientific research has shown that this outdated dogma is in many cases inaccurate and quite often the opposite is true (i.e. linear vs nonmonotonic dose-response curves) [8]

# 2) Active Principle (glyphosate) vs Formulation/product (Roundup)

Regulatory agencies only review the toxicity of the Active Principle alone (i.e. glyphosate) and not the whole product formulation (i.e Roundup) which contains other highly toxic and synergistic "secret" adjuvants. However, a recent landmark peer-reviewed and published study [has alarmingly found Monsanto's Roundup and other pesticide formulations to be 125-1000 times more toxic than their declared Active Principle.

The authors of the landmark study alarmingly found and write:

"We tested the toxicity of 9 pesticides, comparing active principles and their formulations, on three human cell lines[...] Despite its relatively benign reputation, Roundup was among the most toxic herbicides and insecticides tested. Most importantly, 8 formulations out of 9 were up to one thousand times more toxic than their active principles. Our results challenge the relevance of the acceptable daily intake for pesticides because this norm is calculated from the toxicity of the active principle alone. Chronic tests on pesticides may not reflect relevant environmental exposures if only one ingredient of these mixtures is tested alone."

#### Both EPA and EFSA recognize the toxicity of GBH formulations

Both the US Environmental Protection Agency (EPA) and the European Food Safety Authority (EFSA) have publicly recognized the toxicity of glyphosate based herbicides (GBH) formulations.

In its own risk assessment, the EPA publicly admits and states that it evaluated only the "human carcinogenic potential for the active ingredient," not that of "glyphosate-based pesticide formulations." The EPA acknowledges that the formulations may be more toxic than glyphosate and expresses the need to evaluate the toxicity of the entire formulation i.e. Roundup. The EPA is developing a "research plan" with the National Institute of Environmental Health Sciences to "evaluate the role of glyphosate in product formulations and the differences in formulation toxicity."

Similarly, EFSA's risk assessment was based purely on the toxicity of glyphosate alone, not on the complete formulation; although EFSA acknowledged that one common ingredient in glyphosate based herbicides - POE-tallowamine - is more toxic than glyphosate itself, EFSA publicly admits and writes that the carcinogenic potential of GBH formulations "should be further considered and addressed."

### 3) Acceptable Daily Intake (ADI)

The WHO-FAO/JMPR and regulatory agencies worldwide determine and set the Acceptable Daily Intake (ADI) of glyphosate/Roundup based solely on the Active Principle alone (AP) (i.e. glyphosate) and not on the complete product formulation (i.e. Roundup). However, the actual product that is approved by regulatory agencies and copiously sprayed on our food crops, soil, water, air and environment is not only glyphosate (AP) but the whole product formulation (i.e. Roundup). This constitutes a flagrant flaw in the risk assessment of glyphosate/Roundup and a serious health hazard and risk to public health

#### ROUNDUP RESIDUES IN FOOD AND WATER

Roundup residues have alarmingly been found in various common food items i.e. flour, bread, cereals, lentils, peas, beans, potatoes, dairy, eggs, fruits, vegetables, wine, beers, etc., as well as in human urine, blood and breastmilk [10]

Roundup is truly ubiquitous in our daily food supply, as the following recent investigative articles and reports alarmingly reveal [11] [12] [13]

In fact, Roundup is not only used on GMO crops; it is also widely used as a dessicant to dry and kill non-GMO grain crops such as wheat, oats, barley, flax, etc. a few weeks before harvest; it is also copiously sprayed on nuts, lentils, peas, beans, potatoes, fruits and vegetables.

In its "pre-harvest staging guide" Monsanto states: "A preharvest weed control application is an excellent management strategy to not only control perennial weeds, but to facilitate harvest management and get a head start on next year's crop." [14]

Roundup is also present in our daily drinking water supply. A recently published study also found ultra-low dose exposure to Roundup in drinking water to adverse impacts on rat livers and kidneys. [15]

Monsanto of course denies that glyphosate/Roundup residues in our food and water supply are dangerous to our health. "According to physicians and other food safety experts, the mere presence of a chemical itself is not a human health hazard. It is the amount, or dose, that matters," Monsanto senior toxicologist Kimberly Hodge-Bell said in the Monsanto blog; "trace amounts are not unsafe". [16]

However, this false and misleading public statement by Kimberly Hodge-Bell and Monsanto is not supported by scientific evidence and data and is contradicted by the science of toxicology and endocrinology, as I have argued and demonstrated in this paper.

#### Conclusion

To summarize and to conclude, Monsanto and regulatory agencies around the world erroneously claim and argue that glyphosate/Roundup residues in our food and water are safe for human consumption and pose no human health risks; they erroneously believe in the 500 year old and outdated dogma that "the dose makes the poison." However, recent toxicological research has shown that this belief is in many cases inaccurate and quite often the opposite is true i.e. linear vs nonmonotonic dose-response curves.

Furthermore, glyphosate, Roundup and each one of its so-called "inert" and "secret" coformulants have been found to be endocrine disrupting chemicals (EDC) which are extremely toxic to human health at low/minute doses. Endocrine disruptive effects are seen at lower doses but not at higher doses. The studies conducted by industry for regulatory purpose and approval use relatively high doses and are not able to detect these effects.

EDCs in humans are believed to contribute to some cancers, birth defects, reproductive problems such as infertility, and developmental problems in foetuses, babies, and children. These effects are thought to result from very low doses over a long period of exposure or from exposures in critical windows of development, such as foetal development in the womb.

Furthermore, regulatory agencies only review industry-funded and supplied studies on the toxicity of the Active Principle (AP) alone (i.e. glyphosate), not on the whole product formulation (i.e. Roundup) which contains other highly toxic and synergistic "secret" adjuvants. However, a recent landmark peer-reviewed published study has alarmingly found Roundup and other pesticide formulations to be 125-1000 times more toxic than their declared Active Principle.

Regulatory agencies set the Acceptable Daily Intake (ADI) of pesticide residues in our food and water based solely on the toxicity of glyphosate alone and not on the entire formulation i.e. Roundup. However, the actual product that is approved by regulatory agencies and copiously sprayed on our food crops, water, soil, air and environment is not only glyphosate (AP), but the complete pesticide formulation i.e. Roundup. This constitutes a major flaw in the risk assessment of glyphosate/Roundup (and all glyphosate based herbicides (GBH) formulations) and a serious hazard and risk to public health.

Therefore, it is fair to conclude that both the risk assessment of glyphosate/Roundup (and all GBH formulations) as well as the ADI are scientifically flawed and extremely hazardous to human health since they expose us to extremely high levels of endocrine disrupting chemicals (EDC) and glyphosate based herbicides (GBH) residues in our food and water.

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