

International Society of Doctors for the Environment (ISDE)



CALL TO ACTION

against the decision of the European Commission renewing the approval of glyphosate

The standing committee on Plants, Animals, Food and Feed (PAFF) has recently approved the proposal of the European Commission for an implementing regulation renewing the approval of the active substance glyphosate for a period of five years.

Only few days before approval (October 17, 2017), the Environment Committee MEPs (39 votes to 9) called for a full ban of glyphosate in the EU by December 2020 and immediate restrictions on its use.

The Commission reached its decision taking into account the conclusions reached by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), disregarding the IARC findings.

At variance with the IARC, EFSA and ECHA considered toxicological studies provided by industry and not published or accepted for publication in the international scientific literature.

An editorial by a wide group of International authoritative Scientists, published on March 2016¹, strongly supported the IARC statement about glyphosate as a “probable human carcinogen” and criticized the conclusions by EFSA.

According to the cited report¹ EFSA:

- “classified the human evidence as ‘very limited’ and then dismissed any association of glyphosate with cancer without clear explanation or justification.”

- Ignoring established guidelines cited in their report, EFSA dismissed evidence of renal tumours in three mouse studies, hemangiosarcoma in two mouse studies and malignant lymphoma in two mouse studies. Thus, EFSA incorrectly discarded all findings of glyphosate-induced cancer in animals as chance occurrences.
- EFSA ignored important laboratory and human mechanistic evidence of genotoxicity.
- EFSA confirmed that glyphosate induces oxidative stress but then, having dismissed all other findings of possible carcinogenicity, dismissed this finding on the grounds that oxidative stress alone is not sufficient for carcinogen labeling".

Besides the effects of glyphosate on cancer risk, strong evidences point to the fact that glyphosate induces environmental damages (also acknowledged by the implementing regulation) and other harmful non-oncologic effects on human and animal health. The only topic currently under discussion is the precise extent of these risks.

The oxidative stress induced by glyphosate-based herbicides (also acknowledged by EFSA) generates non-cancerous toxic effects also at low doses, mainly in terms of endocrine-disrupting², hepato-renal and metabolic alterations^{3,4}. The environmental and health toxicity of glyphosate is also secondary to co-formulants present in commercial formulations (mainly polyethoxylated tallow amine, POEA)^{2,4-9}, also at concentrations well below the agricultural dilution of 1%².

Also in the presence of (few) residual uncertainties in terms of carcinogenicity, underestimating the relevance of available results from *in vitro* and animal models is not ethically acceptable since, as has been observed reasoning in terms of primary prevention, it "is equivalent to accepting that a potential hazardous effect of an environmental agent can be assessed only *a posteriori*, after the agent has had time to cause its harmful effects"¹⁰. Results already available are sufficient at least to invoke the respect of the precautionary principle^{11,12}, also considering the large number of subjects involved and classifiable as "vulnerable"¹³, and possible interactions between multiple and heterogeneous exposures, overcoming the single-pollutant approach with the measurement of the absorbed internal dose of multiple pollutants (the concept of exposome¹⁴).

In our opinion, and according to scientific available evidences, the implementing regulation renewing glyphosate use for another five years fails to ensure a high level of protection of both human and animal health and the environment, and does not respect the precautionary principle.

The main reasons to annul the decision by the Commission are well and clearly explained in a recent report by Prof. Olivier De Schutter (available at the link <http://extranet.greens-efa-service.eu/public/media/file/1/5422>), who served as the United Nations Special Rapporteur on the right to food from 2008 to 2014.

The nine member States that voted against the proposal (Belgium, Greece, France, Croatia, Italy, Cyprus, Luxembourg, Malta, Austria) should rapidly act to reach an annulment of the implementing regulation, challenging before the Court of Justice of the European Union.

References

1. Portier CJ, Armstrong BK, Baguley BC, et al. Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). *Journal of epidemiology and community health* 2016; **70**(8): 741-5.
2. Defarge N, Takacs E, Lozano VL, et al. Co-Formulants in Glyphosate-Based Herbicides Disrupt Aromatase Activity in Human Cells below Toxic Levels. *International journal of environmental research and public health* 2016; **13**(3).
3. Mesnage R, Renney G, Seralini GE, Ward M, Antoniou MN. Multiomics reveal non-alcoholic fatty liver disease in rats following chronic exposure to an ultra-low dose of Roundup herbicide. *Scientific reports* 2017; **7**: 39328.
4. Mesnage R, Defarge N, Spirox de Vendomois J, Seralini GE. Potential toxic effects of glyphosate and its commercial formulations below regulatory limits. *Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association* 2015; **84**: 133-53.
5. Chlopecka M, Mendel M, Dziekan N, Karlik W. The effect of glyphosate-based herbicide Roundup and its co-formulant, POEA, on the motoric activity of rat intestine - In vitro study. *Environmental toxicology and pharmacology* 2017; **49**: 156-62.
6. Navarro CD, Martinez CB. Effects of the surfactant polyoxyethylene amine (POEA) on genotoxic, biochemical and physiological parameters of the freshwater teleost Prochilodus lineatus. *Comparative biochemistry and physiology Toxicology & pharmacology : CBP* 2014; **165**: 83-90.
7. Lanctot C, Navarro-Martin L, Robertson C, et al. Effects of glyphosate-based herbicides on survival, development, growth and sex ratios of wood frog (*Lithobates sylvaticus*) tadpoles. II: agriculturally relevant exposures to

- Roundup WeatherMax(R) and Vision(R) under laboratory conditions. *Aquatic toxicology* 2014; **154**: 291-303.
8. Mesnage R, Bernay B, Seralini GE. Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity. *Toxicology* 2013; **313**(2-3): 122-8.
9. Seguin A, Mottier A, Perron C, Lebel JM, Serpentini A, Costil K. Sub-lethal effects of a glyphosate-based commercial formulation and adjuvants on juvenile oysters (*Crassostrea gigas*) exposed for 35 days. *Marine pollution bulletin* 2017; **117**(1-2): 348-58.
10. Tomatis L. Primary prevention protects public health. *Annals of the New York Academy of Sciences* 2002; **982**: 190-7.
11. Hau M, Cole D, Vanderlinden L, et al. Development of a guide to applying precaution in local public health. *Int J Occup Environ Health* 2014; **20**(2): 174-84.
12. Lo CF. Risks, scientific uncertainty and the approach of applying precautionary principle. *Med Law* 2009; **28**(2): 283-300.
13. Bracken-Roche D, Bell E, Macdonald ME, Racine E. The concept of 'vulnerability' in research ethics: an in-depth analysis of policies and guidelines. *Health research policy and systems* 2017; **15**(1): 8.
14. Wild CP. The exposome: from concept to utility. *International journal of epidemiology* 2012; **41**(1): 24-32.