Stella Kyriakides, European Commissioner for Health and Food Safety
European Commission
B-1049 Brussels

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Open Letter: Fraud at GLP-certified laboratories

Dear Commissioner Kyriakides,

We are writing to you on behalf of the coalition "Citizens for Science in Pesticide Regulation", a European initiative consisting of over 140 European and international civil society organisations and institutions. The coalition is calling on regulators to improve the current risk assessment procedure and ensure that pesticides used in Europe pose no threat to human health and the environment.

We were alarmed by the recent revelations that the Laboratory of Pharmacology and Toxicology (LPT) Hamburg was found to have committed fraud in a series of regulatory safety tests. LPT had also carried out many of the tests used in the glyphosate re-approval dossier in 2017[1]. This inevitably reinforces public concerns around the validity of pesticides safety assessment, which need to be addressed urgently – an issue we already raised in our public manifesto and experts' White Paper.

According to Regulation (EC) 1107/2009, the European Commission and Member States must carry out an "independent, objective and transparent assessment" of pesticide active substances and products[2] and the European Food Safety Authority must undertake an independent scientific review in line with Reg (EC) 178/2002 of the General Food Law.

However, experimental safety testing of pesticides – the pillar of current pesticide risk assessment and a crucial element for the protection of public health and the environment – is delivered by the agrochemical industry, which has a clear commercial interest in its products being classified as "safe" in order to sell them on the market. This conflict of interest creates inherent bias in the conduct and interpretation of studies. It is a threat to the integrity of the assessment as a whole. [3]

Contracted laboratories committing fraud in order to produce results that please their clients is nothing new. In the aftermath of the Industrial Bio-Test Laboratories (IBT Labs) fraud case in the 80s – which brought into question the safety of 15% of all pesticides used in the US – and of the Craven Labs fraud in the 90s, it was evident something had to change. But instead of setting up an independent and objective system, governments promoted a quality management system, requiring industry and its contracted labs to carry out regulatory tests according to Good Laboratory Practice (GLP)[4] principles. However, GLP guarantees neither the studies' scientific quality nor

[1] Global 2000, PAN Germany, Corporate Europe Observatory, 2020. Factsheet Dangerous confidence in "Good Laboratory Practice"
[2] Article 11(2) and 36 (1) EC 1107/2009.
[3] See Coalition's White Paper Structural shortfall point 1.1. Safety testing for risk assessment is carried out by the company that stands to profit from a favourable assessment
[4] OECD Principles of Good Laboratory Practice (GLP)

their independence, and is mainly "a paper trail" system. If, for example, 10 rats died in an experiment but the technician noted only 3 dead rats in the lab log, there would be no way to trace the truth.

In the absence of effective changes to improve the system, history has inevitably repeated itself. LPT Hamburg was caught manipulating GLP toxicity studies by replacing dead animals with live ones, changing tumour data to "inflammations", and generally distorting data for a favourable result. Despite national inspections, the manipulation of study results in LPT Hamburg continued undetected for 15 years. This is worrisome because GLP regulatory studies are considered reliable for risk assessment by default. Once again, it is evident that we cannot simply rely on GLP to eliminate the inherent bias of industry testing its own products.

LPT Hamburg had provided 24 of the regulatory studies for the re-approval of glyphosate in 2017. including 3 studies on mutagenicity that showed no indication of effects. In fact, all the industry-GLP studies on glyphosate genotoxicity showed that there was no effect. In contrast, about 75% of the peer-reviewed independent scientific literature on glyphosate genotoxicity reported a significant effect, which led the International Agency for Research on Cancer (IARC) to conclude that the mechanistic evidence on carcinogenicity of glyphosate is strong[5]. It would be naïve to consider such a discrepancy a simple coincidence.

Ensuring the independence of pesticide regulatory testing from the agrochemical industry was identified as a key priority to improve the regulatory framework for risk assessment of hazardous pesticides at the EU Chemicals Policy 2030 high-level conference. In addition, the European Citizens' Initiative StopGlyphosate proposed as one of its key demands that "studies to assess the safety of pesticides should not be commissioned by those with a very clear vested interest in their outcome". Yet this issue still remains to be addressed.[6]. In our opinion, a system free of conflict of interest, with costs covered by applicants who profit from selling their products, and where EFSA commissions tests to independent laboratories in a 'blinded' system[7], is the only way of achieving reliable scientific outcomes and effectively protecting the public and the environment.

An important lesson from this latest incident is that GLP studies must stop being considered the "gold standard" in pesticide safety assessment and should be closely scrutinised before they are regarded as reliable. Moreover, independent, peer-reviewed scientific literature should be given equal weight with GLP regulatory studies, as highlighted by the EU Parliamentary PEST Committee, set up in 2017 to investigate the European Union's authorisation procedure for pesticides (Resolution 2018/2153(INI)).[8]

In conclusion, ahead of the publication of the result of the REFIT evaluation of Pesticides Reg (EC) 1107/2009 and Maximum Residue Limits Regulation (EC) 396/2005, we ask you to take urgent measures to increase the level of protection of the public and the

[5] Global2000, PAN Germany, Corporate Europe Observatory, 2020. Factsheet Dangerous confidence in "Good Laboratory Practice"
[6] ECI official website https://europa.eu/citizens-initiative/initiatives/details/2017/000002_en
[7] See Coalition's White Paper Structural shortfall point 1.1. Safety testing for risk assessment is carried out by the company that stands to profit from a favourable assessment
[8] See Coalition's White Paper methodological shortfall point 2.5. Peer-reviewed scientific literature is used in a limited, biased, and unintegrated way

environment against the harm posed by pesticides – and thus to regain citizens' trust. The first crucial step in this direction is to replace the current practice of industry testing its own products with a new, fully independent experimental test system for pesticides. In the meantime, it is necessary to ensure that independent peer-reviewed scientific literature is considered a reliable source of information in the risk assessment process and to acknowledge that industry-funded GLP studies have an inherent bias.

We thank you in advance for your response to this issue,

Kind regards,

The steering group of "Citizens for Science in Pesticide Regulation"

Pesticide Action Network (PAN) Europe; GLOBAL 2000; Pesticide Action Network (PAN) Germany; Corporate Europe Observatory (CEO); Health and Environment Alliance (HEAL); GMWatch; Pesticide Action Network (PAN) UK; Générations Futures; Justice Pesticides; and Environment Justice Support (HEJsupport)