Extensive Database of Studies from Multiple Sources Supports the Safety of Glyphosate

- Eric Sachs, Monsanto Company, eric.s.sachs@monsanto.com, June 9, 2011

A collaboration calling itself the Earth Open Source issued a report this week, "Roundup and birth defects - Is the public being kept in the dark?" that alleges Roundup/glyphosate at concentrations lower than those used in agricultural formulations causes birth defects in animal tests, and that the European Commission has ignored this and other adverse health findings.

The report by Antoniou et al. is intended to draw attention to allegations of glyphosate impacts and to a lawsuit against the European Commission.

"... shortly after the Commission was notified of the latest research showing that glyphosate and Roundup cause birth defects, it quietly passed a directive delaying the review of glyphosate and 38 other dangerous pesticides until 2015. This delay is being challenged in a lawsuit brought against the Commission by Pesticides Action Network Europe and Greenpeace."
<http://r20.rs6.net/tn.jsp?llr=hk4id4bab&et=1105910627822&s=1148&e=001BPSgP6t_JVQXv0nBsBHC43EYGCKpgzgP00swASU52aPqwxohbN035iK3Dn16OAPbhJ1VO7a-Z5WcbmHBtX-XSVgMEVNvFhoiDVJe1hkmLZQLYfTlVSiIP5yXp0Q4RJP4isBm7nqfyGbCCi4AaApaLUN2GK-UuFNnfN0JTbOlr4k=>Page 5, emphasis added, at:

The claim that "that glyphosate and Roundup cause birth defects" relates to research performed by Carrasco and colleagues (Paganelli et al., 2010) in systems involving immersion of 2-cell frog embyos in a glyphosate- based formulation and the injection of glyphosate into one or both cells of the frog embryos and a glyphosate-based formulation into chicken eggs. There are many issues with the quality and interpretability of this work, which was rejected by the German regulatory authority and which has been the subject of published criticism

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http://pubs.acs.org/doi/pdf/10.1021/tx200077h

http://pubs.acs.org/doi/pdf/10.1021/tx100452k

http://pubs.acs.org/doi/pdf/10.1021/tx200086y

While Carrasco et al. attempts to extrapolate from these in-vitro systems to effects in mammalian species and to link this hypothesis to a purported increase in birth defects in humans, these allegations are not supported by the evidence. First, glyphosate data from six sets of reproductive and developmental toxicity studies have been submitted by multiple registrants for review by authorities and there were no teratogenic effects in the animal studies, and second, there is no evidence provided to support the allegations of increased birth defects in humans.

The extensive database on glyphosate is unique because there are multiple primary registrants that have submitted multiple, data sets for regulatory review. Antoniou et al. did not examine all these studies but rather choose individual findings, such as the cardiac findings in one study provided by Feinchemie (1998), to support an argument for adverse effects. However, any individual result can be misleading if it is not reproducible and is taken outside of the context of the weight of scientific evidence. The cardiac findings were not reproducible and did not occur in multiple studies of glyphosate with similar or higher dosing.

In addition, Antoniou et al. highlight supposed teratogenic effects based on a study by Dallegrave et al. 2003 where the authors state, "We may conclude that glyphosate-Roundup is toxic to the dams and induces developmental retardation of the fetal skeleton." A teratogen in animal studies is defined as an agent that induces malformations. Malformations are permanent structural changes that may adversely affect survival, development or function. Experts know that most any compound provided at very high doses may induce maternal illness, and that this can result in the kind of delayed and altered ossification patterns seen at high doses with maternal toxicity in studies of glyphosate. This response to high doses of glyphosate is not evidence of teratogenic effects.

There are extensive datasets to support the safety of glyphosate and glyphosate-based herbicide products. While non-industry studies have not, historically, been included by industry in regulatory dossiers, this information is widely available. Regulatory agencies can search for relevant information and consider information submitted by other organizations - the Paganelli et al. publication is one example.

Additional information regarding the safety of glyphosate, the active ingredient in Roundup-branded herbicides, can be found on the
<"http://r20.rs6.net/tn.jsp?llr=hk4id4bab&et=1105910627822&s=1148&e=001BPSgP6t_JVR0ofZ-VQ3SG_2v0M7qOrprpgpZb0OpdJNzsGSPGssEGNs6hP8WLbmJpahuMCGDF2GbwPL1gaNXq5

Hs3srob2pchnGEMizlwSkIUhrwdSBnUBPZi-9uSD9gIKagEM1fEa51oD93FcbE0Bdk8Q11I80yC5j6-DTYz5iBg6WYqtmGhUCe5>Monsanto website at:

Regulatory agencies around the world have concluded that glyphosate is not a reproductive toxin or teratogen (cause of birth defects) based on in-depth review of the comprehensive data sets available.

Monsanto's statement concerning the Earth Open Source report may be accessed <"http://r20.rs6.net/tn.jsp?llr=hk4id4bab&et=1105910627822&s=1148&e=001BPSgP6t_JVRpX9N5591mVRIf6sPPW7seCsFtgoy8upCJGpniJBcOEk_GFtmvGjHzjpp521CG8zyNZ5AeHfjVPnapNfzhbgdie1HoC2aN2u75p1Ep9OU5DyXGlTbiNNdjA3mftu17YWmbqbNmZKyTQzn7sTwURTjzrG-2mYOzQzjxbkhOeucjYLyx3>at:

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