



January 22, 2014

Submitted to Federal e-rulemaking Portal

Dr. Steven M. Knott
Acting Director, Office of Science Coordination and Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

Re: Docket ID No. EPA-HQ-OPP-2013-0485. FIFRA Scientific Advisory Panel; Notice of Rescheduled Public Meeting. 78 FR 68836. Nov. 15, 2013.

Dear Dr. Knott:

CropLife America (CLA) is pleased to submit the following comments in relation to the upcoming Scientific Advisory Panel addressing, "RNAi Technology as a Pesticide: Problem Formulation for Human Health and Ecological Risk Assessment." CLA is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the U.S. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers. CLA comments on issues that can have broad regulatory implications for crop protection.

RNA interference (RNAi) is a natural biological process in cells; small molecules of RNA modulate or destroy specific messenger RNA (mRNA) molecules following gene transcription, thereby inhibiting gene expression. It is a powerful tool for innovation that has entered the lexicon of biomedical researchers in a short time. Its discovery in 1998 was quickly followed by award of the 2006 Nobel Prize in Physiology or Medicine to Drs. Andrew Fire and Craig Mello for their discovery of the phenomenon in *Caenorhabditis elegans*. Not only have RNAi technologies been adopted as a tool to aid researchers in more rapidly identifying the functions of genes, but their use by the crop protection industry is gaining momentum.

Innovation in agriculture is critical, and RNAi technologies have the potential to become the "next generation" of agricultural tools. Research for the use of RNAi technologies in agriculture spans a variety of areas, such as protecting plants from weeds and pests, novel approaches to increasing yield, and new remedies to improve honeybee health. RNAi can be used to precisely target and control specific plant pests, as well as provide broad-spectrum resistance against a wide range of pathogens.

The importance of innovation becomes even more evident when one considers the pressure on the agricultural industry to feed more than 9 billion people by the year 2050. Although the global population has doubled in the last 40 years, the amount of land devoted to food production

has stayed virtually the same – largely due to past advances in crop protection products and other modern farming techniques. In this light, RNAi technologies emerge as an important new avenue towards sustainable agriculture, potentially allowing farmers to substantially increase yields above current levels without expanding the use of land, water, and other natural resources.

The gathering momentum for use of RNAi technologies in agriculture draws upon the potential these technologies offer for next-generation products as well as solutions to current problems. Whether delivered systemically or applied topically, RNAi technologies trigger a naturally-occurring process in the targeted plant or pest to halt or decrease production of a specific protein, much like a dimmer switch on a light. These technologies have the potential to leverage naturally-occurring processes to offer new modes of action in managing hard-to-control weeds or pests, thereby enabling them to increase crop yields and maintain productivity. This is particularly important, as pressure from resistant and hard-to-control weeds is increasing. Furthermore, when used in combination with other weed or pest control products or technologies, RNAi technologies can help preserve their effectiveness and value to growers.

Finally, it should be noted that there has already been some degree of regulatory analysis of RNAi technologies, particularly with regard to hazard characterization and anticipated data needs for regulatory risk assessment. In July 2013, the European Medicines Agency (EMA) reviewed an RNAi product intended to prevent acute disease in honeybees caused by Israeli Acute Paralysis Virus and concluded that “there is no inherent risk associated with oral ingestion of nucleic acids in general [for humans]”. In addition, the EMA concluded that neither a Maximum Residue Level (MRL) nor a standard full toxicology package was required to demonstrate the safety of RNA to humans from ingestion of honey produced by bees treated with the RNAi product. See

http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2013/07/WC500146575.pdf.

CLA appreciates the opportunity to provide comments in support of the use of RNAi technologies as another key tool in the sustainable agricultural toolbox. Questions or concerns regarding these comments may be directed to me via email at bglenn@croplifeamerica.com or at (202) 296-1585.

Sincerely,



Barbara P. Glenn, Ph.D.
Senior Vice President
Science & Regulatory Affairs