

● INTERVIEW WITH PRESIDENT ANNA RATH

# Vestaron ready to land in Europe

**Authorization has been initiated for this American company to launch a new class of insecticides based on peptides in the European market.**

In a landscape shaken from a regulatory perspective by the new proposed regulation on the sustainable use of plant protection products and the ruling of the EU Court of Justice on the derogatory use of neonicotinoids, the American company Vestaron is landing in Europe by proposing a new class of peptide-based insecticides. “They are just small proteins,” explained Anna Rath, CEO of the company that applied last year for authorization in Europe for one of its biological agrochemicals, Spear®. “Spear has been on the market now for three years in the United States, where we started with fruit and vegetable crops and this year have added soybeans, cotton, and rice. The product has been used on about half a million acres in total and has shown that it can replace synthetic molecules in rotation with other products,” said Ms Rath. “It has the same duration of efficacy in the field as traditional plant protection products,” stressed Ms Rath. “It does not have resistance because it employs a new mechanism of action (MOA) and in the U.S. it implies only a four-hour re-entry interval (REI) with a zero-day pre-harvest interval (PHI), so you can spray and harvest the same day. We are exempt from residue regulations, and the product is soft on pollinators. In addition, we have seen in some of our trials that if you replace a chemical synthetic insecticide with our product,



sometimes you can wait longer before having to do the next treatment because it has kept the beneficial insects alive.” In short, Spear offers the efficacy of a traditional chemical pesticide, but with the safety and environmental profile of a biological molecule. “So far in the United States,” continues the Executive, a 2016 recipient of the Rosalind Franklin prize for women’s leadership in industrial biotechnology, “we have received no complaints either about efficacy or yields, and this is not something you often hear about with biocontrol products.” In addition to the U.S., the product is marketed in Mexico, and “within a few months, we should have approval for sales and marketing in Canada.”

## The approach to the European Market

But the approval process in the EU will be longer – three and a half years in total. Rath has begun attending meetings in Brussels very assiduously because she sees room to get it done sooner. The Court of Justice’s ruling on neonicotinoids has made it clear once and for all, derogations are meant for products that are not yet authorized, not for those that have been banned. The new Vestaron-branded product meets the first profile, and Rath argues that it could be useful to an Italian producer grappling with, for example, Tuta absoluta. “The European Commission,” emphasized Vestaron’s president, “suggested to us the path of emergency authorization. If there are growers in Italy who would like to apply for emergency use

authorization, we could go to market in a limited way, and specifically for that particular tomato pest much sooner. And since we have already submitted the request to the EU, we have the whole package.” But Vestaron also wants to bring the experience of U.S. regulation to Brussels. “We are working on two major policy goals in Brussels,” explains Rath. “The first is to expand the definition of biological control to include solutions like our peptides, and the second is to support faster procedures for market access. And this exists, among others in the United States, where there are two different pathways – one for conventional chemicals, and the other for products like ours. Regulatory studies still have to follow the rigorous standards of chemistry,” she points out, “but there is a phased system whereby if a study meets some of the criteria in the first phase, we don’t have to submit the others. Typically, 300 studies have to be submitted for the application of a synthetic molecule, while we have about 40.” Vestaron is interested in landing in Europe in a big way, Rath assures, even opening plants in the EU at a time when others are thinking of relocating to the U.S. for the benefits of the Inflation Reduction Act. “For us, it is obvious that if we have a presence in the EU market, we will open plants here.”

## How peptides work

Peptides have interesting properties. “What we had to learn how to do was to couple our peptides with what are called intestinal disruptors to create small ulcers in the insect so that the peptide can move through the intestinal wall and reach the target receptor. The intestinal disruptor that we use is the *Bacillus thuringiensis*, which is specific for lepidopterans, and selective for bees. In the production process, we use some genetically modified yeasts, “but there is no GM material in the final product,” Rath points out. “Not even the nucleic acid remains – the final product is just the peptide, an enhanced peptide not found in nature, that is made entirely of naturally occurring amino acids. That is the important part because that’s what makes it safe for humans and the environment.”