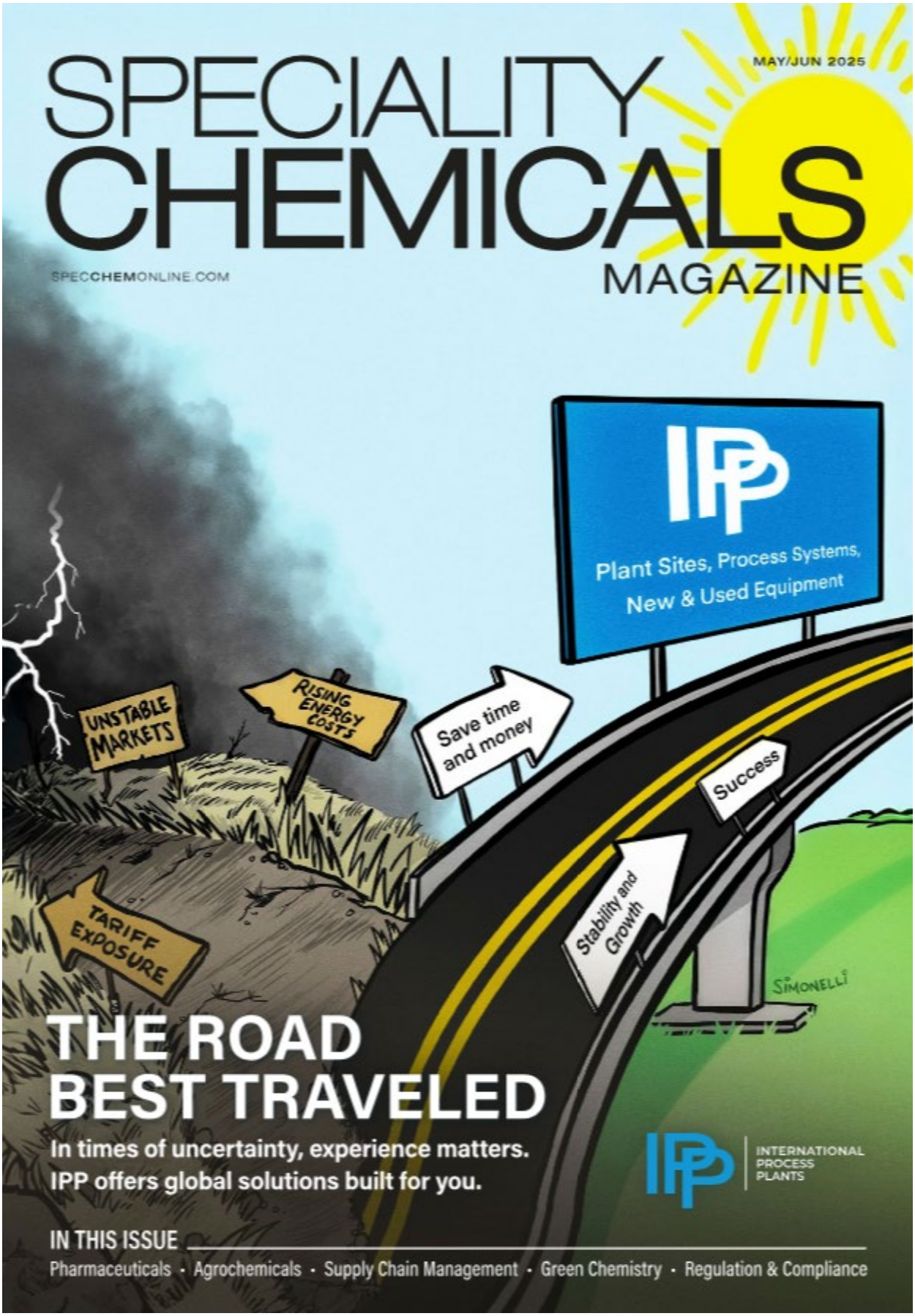
SPECIALITY CHEMICALS MAGAZINE

MAY/JUN 2025

SPECCHEMONLINE.COM



THE ROAD BEST TRAVELED

In times of uncertainty, experience matters.
IPP offers global solutions built for you.

IPP | INTERNATIONAL PROCESS PLANTS

IN THIS ISSUE

Pharmaceuticals · Agrochemicals · Supply Chain Management · Green Chemistry · Regulation & Compliance

From fungicides **to vaccines**

Botanical Solution has found a new application for its lead product that will take it into a whole new market. We spoke with CEO **Gaston Salinas**

The remit of *Speciality Chemicals Magazine* has always been to cover the application of chemicals and materials, often the same chemicals and materials, horizontally across multiple applications. Often, specific chemicals turn out to have uses that were never envisaged when they were first developed. That applies to natural as well as synthetic products.

Someone who knows that as well as anyone is Gaston Salinas, CEO of Botanical Solution (BSI). The company originally came into being to develop a natural biofungicide derived from a tree from his native Chile, *Quillaja Saponaria*. Now the focus has broadened to include applications in pharmaceuticals, which are potentially far more lucrative.

BSI grows *Quillaja Saponaria* in the lab for optimal yields

Initial growth markets

The company itself grew out of the work of co-founder Gustavo Zúñiga. Having grown *Quillaja Saponaria* in the laboratory because of the difficulties in sourcing material in the wild, he discovered that his plants generated different kinds of phenolic compounds with fungicidal activity. When subjected to stress conditions such as light exposure and changed media culture composition, he was able to generate these compounds consistently in large volumes.

BSI was founded in Santiago in 2013 and moved to Davis, California, one of the major centres of biopesticide research, in 2019. Its initial product, known as Quillibrium globally and Botistrop in Chile, is an 8% extract from tissue-cultured *Quillaja Saponaria* plants. At 30-60 days, these are inoculated into bioreactor systems for rapid growth in the right conditions for the secondary metabolites with biofungicidal activity to develop.

Following years of field tests, Quillibrium was registered and is now used for the prevention and control of *Botyris cinerea*, *Altenaria altenata*, powdery mildew and sour rot. This affects many of the high-value crops that Chile and Peru export over long distances, such as blueberries, grapes and other fruits and vegetables.

Serendipity strikes

A chance conversation Salinas had with a Californian pharmaceutical CEO led to the discovery that *Quillaja Saponaria* also produces the vaccine adjuvant QS-21. Indeed, BSI's *in vitro* approach enables it to produce a more sustainable QS-21 than can be produced from saponin concentrates in the bark of wild-grown trees.

The timing of this discovery could hardly have been better. QS-21 sourced from the bark of *Quillaja Saponaria* had been studied for some 30 years, but had not been used in a commercial vaccine until 2017. The COVID-19 pandemic gave it a huge boost because Novavax used it in its COVID vaccine.

QS-21 stimulates the human immune system and has a lower toxicological profile than other saponins in the same family. It has also been used in treatments for shingles (Shingrix from GSK), respiratory syncytial virus (Arexvy, also from GSK) and malaria vaccines. However, this has been almost exclusively in blockbuster drugs, because of its high cost, up to $400,000/g.

"All Big Pharma companies with an interest in QS-21 have been waiting for a more robust supply chain to be in place before they commit to using it for vaccine development," Salinas says. If it could be produced more economically, there would be great potential for it to be used in many other vaccines. BSI therefore signed a partnership with Croda International to scale up development and manufacture.

BSI claims that its QS-21 achieves up to 99% purity in a market where 95% is currently the gold standard. This has been confirmed in tests carried out in partnership with some major pharmaceutical companies. These tests also proved that the product is biochemically equivalent to traditionally sourced QS-21 and equally active biologically.

Funding for expansion

The company has recently raised $23 million in Series A funding and will soon start working on Series B funding. The money is being used to secure its position in both markets.

The big change, Salinas says, has been BSI's ability to make its own end-use product, relying on proprietary purification processes.

"The main reason for following that route is that we found out while we were working on scale-up that there was a major flaw in the downstream manufacturing process," Salinas explains. There was also a sustainability issue: to generate the product at kilogram scale for billions of doses would have required heavy use of organic solvents and high disposal costs.

In 2024, BSI succeeded in developing new methods from hazardous organic solvents and was also more cost-effective. It will still work with Croda to roll out the product, however. Salinas expects the first GMP materials to be made available to pharmaceutical companies in 2H 2025. He will make a more detailed announcement on this at CPHI Americas in Philadelphia in May.

The "really exciting news", he says, is that Croda is not only enabling BSI to accelerate the mass adoption of QS-21 as a stand-alone compound but has also made significant investments in developing clinically relevant adjuvant systems that need QS-21 in order to work and are planning to make them available to other vaccine developers who might need them.

"There is clear value that both parties bring to the table," he says. This will address demand for highly efficacious vaccines in high-income countries, but the real long-term aim is make them available "at the right price" for the malaria vaccines that he believes "will change the face of underprivileged regions across the world."

There has been quite a learning curve in getting into the pharmaceutical industry, Salinas agrees. The two are completely different in many ways, not least the economics of product development and securing approval, albeit that long timelines are involved for each. About the same level of effort and energy are needed but the price at which QS-21 is sold is orders of magnitude higher in pharma than agro.

Agro still important

BSI will still have "a significant revenue stream" from the agrochemical business. Quillibrium is now being distributed by Syngenta in Chile and Peru, with Mexico to follow next year. Brazil is a big target, because the market is so big and registering a new biological is much quicker than in other countries in the region.

The US and then the EU, where already long registration timelines continue to grow, will be the next priorities. However, Salinas recognises the value of having a product registered in the EU. "It is a long journey, but we are committed to making it happen," he says. More details on a global distribution for Quillibrium are expected to be announced later this year.

The company is now looking at opportunities in other biocontrol products over the next five years, also working with different plant species, and is as close as it has ever been to registration and field-testing for these. To date, over 150 different species have been screened for biological activity, mostly also native to Chile. That is only the starting point, of course: registerability, the IP landscape and manufacturing challenges lie ahead before any compound can go towards commercialisation.

Some of the most promising are bioherbicides, bioinsecticides and bionematicides. The biofungicide market is already rather crowded and Salinas sees limited scope for developing new ones unless they clearly exhibit superior control and efficacy but looking for new bioherbicides "is a big deal for us".

"We are committed to keeping the agrochemical business running, but in terms of value creation and meeting investors' expectations, what we are doing in the pharmaceutical space is what will have the greatest impact," he says. ●

BSI scientists discussing the use of Quillaja Saponaria in vaccines

Gaston Salinas
CEO
BOTANICAL SOLUTIONS
gaston@botanicalsolutions.cl
www.botanicalsolutions.cl