

Inside Citrefine's global regulatory team

Jacqueline Watson, Managing Director, Citrefine International Ltd

Insect repellents, and the active ingredients within them, are regulated to ensure that they are safe for both people and the environment, and that the claims made on product labels do not mislead the consumer. While these regulations are important for the ethical and safe sales of insect repellents, the registration process is complex - often with long lead times and potential pitfalls. In addition, regulatory requirements vary widely around the world, with each jurisdiction having its own rules governing exactly how insect repellents can be produced and marketed.

To ensure that our customers are well supported through the regulatory process, Citrefine has a strong team of specialists who are focused on the regulation of Citriodiol® and Citriodiol® products. Each team member is responsible for a specific territory to help our customers navigate the complexities of the regulatory process in their target market, either through direct knowledge or by recommending consultants who can assist them. This approach helps our customers overcome potential obstacles that might otherwise slow down their route to market, as well as allowing them to better gauge a realistic timeline for when their products can enter the stream of commerce.

The regulatory team is headed up by Genevieve Faherty, Regulatory Affairs Director, who has been part of the Citrefine team since 2007 and oversees all jurisdictions. She manages Citrefine's regulatory team to ensure registrations of Citriodiol® formulations are maintained and expanded and has been the lead in obtaining Citriodiol®'s approval as an active substance around the globe. Through this experience, Genevieve has developed an extensive knowledge of the safety and efficacy dataset that support Citrefine's active substance and formulations. This allows her to advise customers on the most efficient solutions to achieving their regulatory goals. For example if one of our customers wants to make a claim about their product's efficacy in repelling ticks, Genevieve would likely start by considering what the efficacy requirement is for the jurisdiction, if data on a related formulation already exists and how to bridge to that data most effectively. If needed, she will put the customer in touch with laboratories and/or consultants who could develop new data to support the desired claim.

As part of this process, either through her own team or by referring customers to appropriate regulatory consultants, Genevieve will work to ensure testing protocols are in line with the jurisdiction's specific requirements. If the customer has more limited experience in reviewing efficacy data for repellent products, she is happy to work with them to interpret and analyse the data as it relates to potential label claims - helping customers make the most of the data that they have developed.

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Key challenges in insect repellent regulation

One of the biggest challenges in the regulatory process is the level of uncertainty and subjectivity among regulators evaluating product registration submissions. This can mean that identical products could have different age restrictions imposed upon them if a regulator were to view underlying safety data more or less conservatively, or an approved claim one month could even be unexpectedly revoked the next. While these are more extreme examples, inconsistencies like these, combined with a lack of certainty about timing and data requirements, are a reality in the regulatory world. Providing experts who can flag potential challenges before a final decision upends a company's marketing scheme, is another benefit our regulatory team strives to offer.

How Citrefine helps its customers to overcome these hurdles

While this uncertain landscape can be difficult to navigate, our regulatory team has been doing it for a long time. With their specialist experience, the team understands what to expect from certain authorities or can recommend consultants who can assist where we cannot.

The team has also developed strong relationships with the individuals who manage the regulation process, which can prove invaluable when, for example, seeking feedback on why something in the regulations has changed. When, recently, a label approval with a 'DEET-free' claim was followed just a few months later by a 180 degree reversal by the regulatory agency, our team was able to gain a rapid understanding that the change in regulation was actually being applied to all biopesticides, and would also apply to the less regulated category of insect repellent products known informally as "25(b)s". This context helped our customers' marketing departments better position the change, knowing that all of their competitors were or would be dealing with the same issue.

In addition to maintaining relationships with regulators in order to understand changes to rules and potential challenges, our team undertakes regular professional development, attending conferences every three-to-six months to gather insights into the key conversations surrounding regulations around the world. They can, therefore, help keep customers informed if there is a major change expected before it becomes an issue.

Importantly, our team always approaches registrations with utmost care and attention, and strives to provide robust evidence to the best standards and in a timely manner. Our team's expertise and transparency support its good reputation among reviewers and we believe this reputation also reflects well on the submissions of our customers that rely on our data or expertise. While this may not speed up the review process, it can certainly minimise risk of unnecessary delays if materials are missing in a submission or not viewed as well-founded scientifically.



Why this service is so important for our customers

Insect repellents are regulated in very different ways across the world, so much so that, while some countries will classify them as cosmetic products, most others consider them to be (bio)pesticides. Pesticide regulation is typically far more stringent than cosmetics, and the unique problem that insect repellents face is that pesticide risk assessments are set up for substances with a less favourable toxicity profile. So, in territories where insect repellents are classified as pesticides, despite being derived entirely from an essential oil, Citriodiol® may have to be assessed with many of the same assumptions as rat poison and, because our product is dermally applied, this can be really difficult.

Since Citrefine was founded, we have been doing the leg work to ensure we can solve the giant puzzle that is the global regulation of insect repellents. We're continually making investments to develop the strongest datasets to support the most efficient routes through the registration process. We do this so that we can pass this knowledge onto our customers and, when insect repellent producers purchase our pre-approved formulations, they can take advantage of back-to-back registrations allowed in many jurisdictions or gain a trade permit to be able to use our master registration with minimal delay. By understanding our customer's specific needs, and combining this with our knowledge of the regulatory field surrounding this specialist product, we are committed to helping our customers bring their Citriodiol®-based product quickly and efficiently to market.

