

# Growing pains of EU agchem regulatory regime

by Robert Birkett



**Complications and confusions were the running themes of a roundtable of industry representatives and regulators as they debated the five-year anniversary since the implementation of European agrochemical Regulation 1107/2009 at the 2017 Agchem Forum in France this month. revenues to \$4.2 million in the first quarter of 2017.**

Mike Carroll, Arysta LifeScience's head of R&D Europe Middle East Africa complained that the EU was implementing a system that confused applicants. "Other global reviewer countries, such as the US, or Australia specify required studies, protocol and timelines from the start of an application that companies can at least plan with; not in the EU," he said. "It seems the opposite case in the EU once companies have guessed the requirements based on guidance documents and regulations, they receive a list of data gaps from the EFSA [European Food Safety Authority]. Can this change?" he asked.

The UK Chemicals Regulation Directorate (CRD)'s Donal Griffin sympathised, stressing his opinions were not necessarily those of the CRD. "There is a list of studies we demand, but perhaps not a clear one. We have had up to four applicants for a substance each with a separate dossier, each of which we assess in full and that may explain why we are behind on the renewals programmes."

Johan Axelman, strategic adviser, authorisation and guidance, for the Swedish Chemicals Agency agreed that the situation in Europe was confusing. “We need greater predictability, as it is already confusing enough. Data call-ins may be the way to go.”

Christian Prohashka, department head for residues behaviour, of the Austrian health and food safety agency, the Ages, pointed out that applicants know in advance what data requirements need fulfilling. He said that certain data gaps could be clear, such as those that lead to a non-approval of an active ingredient, or the need for confirmatory data, but many other gaps resulted in “a kind of data call-in system, that is far from perfect”.

Mr Carroll believes that the EU is moving “slowly but surely” to a data call-in system. He raised a further contention: the separate approval processes for actives and their products. “Uniquely, in Europe after the painful approval of an ai, you then go onto the reauthorisation process for a product based on the same ai in member state after member state. Elsewhere in the world that is taken care of in the review. With a risk envelope approach you could streamline the reauthorisation of products.

“The current system comes into disrepute, and the NGOs have a valid point complaining for example with glyphosate [herbicide] that we are still selling products with old labels. A raft of new risk assessments around endocrine disruption – an issue lacking scientific consensus – are ready to be dropped into the mix even as we have a massive review backlog of ais. How will that be handled seemingly without a prepared process?”

Mr Prohashka understood the concerns of industry and growers over the prolonged renewal process. “I doubt industry is happy that the review process for products is lasting longer than expected, as a longer review would leave less time for formulation changes among other things, so we all try to act to counter this such as with data call-ins.”

Bernd Brielbeck, senior manager, regulatory affairs, agrochemicals and biopesticides, at German regulatory consultancy SCC, denied noticing any data call-in system in use. “We have had complete reassessments on almost all ais in AIR-3 [third round of ai renewal process].”

Mr Prohashka seemed to agree. “We have completely new assessments. The original intention as I understand it was to focus on data requirements, but the result has been new assessments.”

Mr Griffin answered a query whether assessments every ten years were needed: “It’s what the politicians wanted, bringing renewals up to the latest standards. There have been new data requirements that have demanded few new studies. The big change has been the governance guidance.

“The UK approach was to look at assessments of ten years previous and if still happy with the endpoints accept the assessments, but EFSA was adamant that we reassess under the latest guidance. That has created a large amount of work.”

A Bayer delegate described “recent examples” of how a rapporteur may submit a report for ai approval only for the EFSA to see certain studies as invalid and recommend non-approval. “The Commission will then follow EFSA. What does the rapporteur think of that, and where is the communication with EFSA?”

Mr Griffin admitted “that sounded familiar”. He said it was frustrating, but it was an EU process and the EFSA issues the wider EU view, following third-party comments.

Mr Griffin also replied to a similar concern on unpredictability and the misapplication of guidance. “We are often asked when a dossier should be prepared for product re-registrations, and the answer is to wait for the EFSA conclusion rather than the rapporteur’s. That is a good indicator of the direction things are heading.”

A BASF delegate wanted another confusion cleared up in the multi-nation system. After submitting a dossier with

one authority, he learned the rules and applied them with another application only to find that authority followed different rules. “This happens at ai level, but more so at product level.” He gave an example of an authority taking EFSA conclusions for endpoints, another using a guidance document, and a third a mixture of the two. He praised the reported meeting of EU central zone authorities regularly meeting to discuss such issues. “Why not align methods formally?”

The CRD delegate said that a recent example of a steering committee agreement to change endpoints was met with no clear mechanism to communicate the change. “The Commission rejected our request to publish the changes as they do not see it as their role.”

Mr Prohashka insisted that there was a rule to be followed on the agreeing and selecting of endpoints that most member states accept.

The Forum started with a debate ranging across the EU’s shared decision-making process on pesticides, the comitology system involving the EFSA, the Commission and member states, the ongoing controversy over glyphosate’s pending approval renewal, and the roles of social media in pesticide industry and regulation.

Mr Brielbeck noted that glyphosate had the same carcinogenic classification as coffee. This echoed the comments of one speaker at the debate when cautioning on the use of media in debate around agrochemicals. An industry representative openly admitted a pesticide’s toxicity in a broadcast interview. To a question whether it had cancer properties he answered: Yes, but less than toothpaste. The quote was edited after the word, “yes”.

Julie Girling, a UK MEP, complained that this revealed the obstacles industry faced with media. She also highlighted that too few politicians had the courage to stand up for the industry, lest they be targeted on social media. She noted that despite her own attempts, she eventually dropped Twitter due to the abuse she received on the platform.

However, she supported the comitology system including potential changes that would bring more decisive actions. On the glyphosate controversy, she supported the Commission’s caution following the UN WHO International Agency for Research on Cancer finding that it was “probably carcinogenic”, but that subsequent assessments meant the Commission should show the courage to approve even if member states fail to reach a majority opinion either way.

A vote on glyphosate’s EU re-approval is due next month.

One delegate at the debate complained that his company may abandon Europe due to the lack of biopesticide approvals. Mr Brielbeck said that this was due to a lack of definition of such products in the EU. “Europe goes by low-risk substances, not biocontrols.”

### Low-risk ais

Mr Brielbeck cited a “tsunami” of regulations, directives and resolutions on low-risk substances in EU agrochemicals policy in a subsequent presentation that morning. He said that industry was shocked by the introduction of 1107/2009 with its use of hazard assessments and cut-off criteria – in which ais could be lost due to hazardous properties without assessment of risk – of candidates for substitution and of comparative assessment. “But we overlooked that it is also the basis for change for agriculture in Europe.”

He said the old directive, 91/414, was mainly about regulatory issues and getting a grip on what was already authorised, but the new regulation defined an altered future for agriculture. “That future is now.”

He focused on: the 2012 Sustainable Use Directive “for agrochemicals when it should be called sustainable agriculture”; the Commission’s issue of its strategy on sustainable growth: a bioeconomy for Europe; Regulation 1291/2013 establishing Horizon 2020 with funds of €80 billion (\$96 billion at the current rate) of public money to industry to foster research on “low-risk biopesticides”; and a more recent European Parliament resolution bringing such a bioeconomy into focus.

The Parliament resolution of February 2017 on low-risk pesticides of biological origin calls for: clear criteria for defining low-risk ais for the development and use of such pesticides; and for non-chemical alternatives such as biological controls to be given provisional approval for use and priority for evaluation; for faster approval processes to increase the availability of low-risk crop protection on the market and reduce the risk of resistance to ais and the effects on non-target species linked to commonly used products; as well as inviting member states to include the use of low-risk biological origin pesticides in their national action plans on environmental and of human health protection.

“The resolution stipulates approval process not authorisation process, so it is demanding that the ais be approved faster, not products – which is already stipulated with a 120-day for low-risk products.” The SCC executive noted that low-risk products of biological origin are to be used in national action plans. He added that Europe’s preference for low risk did not explicitly favour biopesticides, but “we seem to be going for the first time towards saying natural is better than artificial”.

“Currently, there are only ten approved low-risk substances. But in AIR [active ingredient renewal]-4 programme, the Commission is pushing for low-risk ais to answer the demands of parliamentary resolutions.”

The group of ais to be assessed under AIR-4 with expiry dates before April 2019 includes 25 of the 51 ais that are “presumed to be low risk”, while the second group includes 38 ais all of which are “presumed to be low risk”.

“AIR-3 had no such clear grouping, but AIR-4 has clear grouping of promoting low risk and getting rid of those falling under cut-off criteria.” There is a third and fourth group, with the earlier one including 13 “that may fail to satisfy approval criteria”.

When discussing efficacy evaluations, Mr Brielbeck insisted that “science is coming back” at least with evaluations of low-risk products.

A 2017 Regulation 1432 amending 1107/2009 has made a more detailed and specific categorisation of a low-risk ai. “But what is new in this Regulation is that a naturally occurring ai other than micro-organisms and that does not correspond to any of the detailed categories may be considered as being low-risk, even if it is persistent.”

The Dutch board for the authorisation of plant protection products and biocides, the CTGB, says: “In general all micro-organisms which fit the approval criteria and do not show multiple resistance to anti-microbials used in human or veterinary medicine will be considered as low-risk substances. Some exceptions however are made. For example, the recently approved *Beauveria bassiana* 147 was not granted low-risk status due to a relevant metabolite.”

Meanwhile, the Commission is still working on a guidance document for low-risk criteria.

Mr Brielbeck noted the lower fees for low-risk ais and products, and that Parliament has requested quicker authorisation processes for actives, and there is already a 120-day limit for product approvals, except under 1107/2009’s Article 43 for renewals in which all products have a 12-month limit after the renewal of the ai.

The Forum covered various subjects within the regulatory stream. They included the EU’s zonal approval regime, and the ongoing ai renewal process. They will be covered in a forthcoming article.

*The Agchem Forum took place in Nice, France on September 6th-7th.*