HBW INSIGHT
CITELINE COMMERCIAL

19 Dec 2022 | **Analysis**

EU Reg Consultant On CLP Revisions: Take A Breath, Cost It Out, Consider 'Lobbying And Pushing Back'

by Ryan Nelson

Louise Witter of UK-based Chemical Legislation Professionals spoke with HBW Insight ahead of the European Commission's 19 December adoption of a proposal to revise the CLP by introducing new hazard classes, including for endocrine disruptors.

The European Commission adopted a proposal on 19 December to amend the Classification, Labeling and Packaging Regulation (CLP) with new hazard classes for endocrine disruptors and chemicals that do not break down in the environment and can accumulate in living organisms or potentially end up in drinking water, it says.

Louise Witter, director and principal consultant at UK-based Chemical Legislation Professionals Limited, who spoke with HBW Insight on 8 December, recognized that the initiative was on a fast track to adoption, despite serious concerns raised by stakeholders.

She noted that an ad hoc meeting of the Competent Authorities for REACH and CLP (CARACAL) was held on 29 November to discuss latest revisions to the draft regulation and CLP annexes dated 18 November and 17 November, respectively.

CARACAL is composed of representatives of Member State competent authorities for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and CLP; competent authorities of EEA-EFTA countries; as well as a number of observers from non-EU countries, international organizations and stakeholders.

The CARACAL meeting followed a roughly month-long public consultation that closed on 18 October. The European Commission first announced its intention to revise the CLP, including by introducing new hazard classes "such as endocrine disruptors," in April 2021. It launched an

open public consultation in August 2021 for a period of 14 weeks and then a six-week targeted consultation in November 2021 with Member State authorities and national helpdesks, academia, NGOs, and duty holders.

The analysis "showed that business entities and associations were mostly not in favor of introducing new hazard classes," the Commission noted. "Those stakeholders argued that such introduction would lead to potential information overload in hazard communication, distort the level playing field of international trade, and lead to cost increases for various activities."

Source: Louise Witter

Detractors also pointed to potential overlaps of the new hazard classes with existing ones for classification and labeling, and questioned whether CLP – which requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package hazardous chemicals appropriately before placing them on the market – is the proper mechanism for addressing chemicals' endocrine-disrupting properties.

The *EU proposal* uses the World Health Organization definition of endocrine disruptor as the basis for its proposed hazard class, a decision generally applauded by industry. However, the American Chemistry Council suggested in comments that "in numerous instances" the regulation deviates from the WHO definition by seeming to use the terms "endocrine activity" and "endocrine disruption" interchangeably.

"The [WHO] definition makes it clear that to classify a substance as an 'endocrine disruptor,' there must be a level of certainty that a direct causal link exists between an endocrine mode of action and any corresponding adverse effect observed in an intact organism. … As currently drafted, the proposed definitions included in the [EU] delegated act do not consistently reflect the causal link requirement of the WHO definition; nor do they consistently include a direct reference to an adverse effect," the ACC said.

The CLP is based on the United Nations' Globally Harmonized System (GHS), and throughout the consultation process on the EU proposal, companies and trade associations argued that new hazard classes should only be introduced to the CLP as a GHS implementation measure.

Clearly the Commission has no intention of waiting on UN GHS. According to today's announcement, the *Commission Delegated Act* introducing the new hazard classes, and associated

annex changes, are expected to enter into force early next year, after scrutiny by the European Parliament and Council.

> *"One of the things that I noticed is every time there's a big regulatory change, we have an extinction event of suppliers." – Louise Witter*

Witter noted that the CARACAL meeting at the end of November was "reviewing or discussing the very final draft. So although they said 'draft' on them, they also said 'final draft' on them. And even to get to that draft, they didn't want any comments. They explicitly asked for no comments on the previous draft. So you could see where the wind was blowing here."

She expected the draft final regulation to go out for checking around 19 December, initiating a roughly two-month process. Given the holiday season, during which time "it'll be sitting on people's desk," Witter expects those two months to pass in a blink.

Some revisions to the regulation are likely to be welcomed by industry. Notably, non-animal data that provides equivalent predictive capacity as animal testing data can be used as a potential basis for endocrine disruptor classification under the proposal adopted by the Commission, addressing concerns raised by cosmetics stakeholders in an increasingly cruelty-free industry already subject to EU animal-testing prohibitions.

Additional changes from previous drafts include a 6-month deadline extension (from 18 to 24 months) for new substances to be classified in accordance with the proposed criteria, which cover endocrine disruptors as well as substances with persistent, bioaccumulative and toxic properties (PBT); substances with very persistent, very bioaccumulative properties (vPvB); and substances having probable serious effects on the environment due to their persistent, mobile and toxic (PMT) and very persistent, very mobile (vPvM) properties.

However, industry stakeholders asked for more. Noting that downstream users marketing mixtures need time to respond to updated classifications of all compositions via Safety Data Sheets – including existing substances, which would have 42 months to come into compliance – BASF SE requested a compliance timeline of at least 42 months for new mixtures versus 36, while supporting the proposed 60 months for existing mixtures, which they maintained is "not exceedingly long."

BASF, among others, also argued that the regulation's entry into force should be contingent on the availability of comprehensive guidance documents "containing examples and detailed explanations" to facilitate compliance, which industry stakeholders should have a role in developing.

The German chemicals firm held, though, that guidance alone cannot cure imprecise and vague phrasing that needs ironing out in the legal text itself.

Witter noted, "They are quite clear within the regulations that they've done multiple consultations on this and not everyone is on board. You know many Member States had problems with this, lots of companies had problems with this, some of the regulators were a bit, sort of, 'Is that going to work?'"

She added, "It's quite clear that they're not taking on board anything other than the most practical things that are coming out of the consultation that might throw up immediate problems."

Longer-Term Problems

Cosmetic products in finished states are not subject to CLP requirements. However, CLP classifications can impact ingredient use in cosmetics, including ingredients deemed to have carcinogenic, mutagenic or reprotoxic (CMR) properties. CMR substances are banned from use in cosmetics under the EU Cosmetic Products Regulation if they fail to meet specified criteria, including affirmative safety review by the Scientific Committee on Consumer Safety. (Also see "*Cosmetics Europe Strategizing To Defend Ingredients Flagged As Endocrine Disruptors, CMRs*" - HBW Insight, 8 Jan, 2019.)

The Cosmetic Products Regulation also is under revision in parallel with the CLP and REACH, with a stated aim to address use of endocrine-disrupting substances. (Also see "*EU Starts On Proposal For Tackling 'Most Harmful' Chemicals Under Revised Cosmetics Reg*" - HBW Insight, 23 Jun, 2022.)

Compared with endocrine disruption, Witter pointed to a hazard that's better understood and accounted for in CLP criteria. "A good example is something like a flammable liquid. You would do a flashpoint, and you've got a range of criteria. So if the flashpoint is between X and Y, the product is flammable category *whatever*, and then you apply your H statement to it. So you've got this discernible test," she said.

For the Commission's proposed new hazard classes, companies may need to use a suite of different tests to assess the hazard criteria's applicability, raising significant concerns about resource expenditure.

Moreover, “it’s not even clear whether the testing houses can actually do any of the tests needed, or all of the tests needed, in order to prove these criteria,” Witter said. “You’re talking about having experts who are able to apply expert judgment and weight-of-evidence approaches to new test regimes and new classes.”

She added, “These people are going to be busy.”

‘Green’ At Any Price?

Beyond the particulars of the Commission’s proposal, there are objections to its chosen process for making the CLP changes.

“The insertion of new hazard classes and their criteria into the CLP Regulation is one of the primary commitments of the chemicals strategy for sustainability, which is a building block of the European Green Deal,” the Commission explains. (Also see "*EU Chemicals Strategy Stands To Transform Cosmetics Regulation*" - HBW Insight, 3 Nov, 2020.)

According to Witter, “It is actually not consistent with the process for how the regulations are supposed to be updated. So there’s even a process quibble.”

Witter, who has degrees in law and marine and environmental biology, suggested that more concerted pushback from the chemicals industry – already a highly regulated space – may be necessary and warranted.

She noted, “What happens when you when you have changes like this is not just the obvious stuff where you have to update registration dossiers, reclassify things, relabel things, redo your data sheets. It’s not just these sorts of knock-on activity impacts. … You [also] have de facto or actual blacklisting.”

Supply chain entities can decide suddenly not to accept any materials with certain hazard classifications, she said. “So this seems like an almost backdoor way of restricting products.”

Witter continued, “One of the things that I noticed is every time there’s a big regulatory change, we have an extinction event of suppliers. … Quite often these are smaller companies in specialty chemicals, run by families, and they just drop out of the system because they say, ‘Well, I’m planning on retiring in five years. How much is it going to cost me to do this? How much head space will I need to make for it? What will be the overall cost-benefit analysis?’ And they just retire early.” ((Also see "*Over The Counter 19 December 2022: CLP, Cosmetics And New Hazard Classes In The EU’s Haste To Be Green, With Louise Witter*" - HBW Insight, 19 Dec, 2022.)

Givaudan’s Greg Adamson, senior vice president, global regulatory affairs and product safety for fragrance and beauty, said in June that new hazard classifications brought forth by the EU’s

chemicals strategy for sustainability stand to impact 60% of fragrance ingredients across all aroma categories, including many naturals, that are safely used today in thousands of cosmetics products. (Also see "*EU Sustainable Chemicals Program Could Impact 60% Of Fragrance Ingredients – Givaudan*" - HBW Insight, 30 Jun, 2022.)

"It's a lot to take on for an industry that's already pretty responsible in a really fast-moving regulatory field the last couple of years, which has been really destabilizing for a lot of people," Witter said.

> ***"A lot of people get shouted down by, 'Oh, you're an environmental denier, you don't care about fish' and things like that."***

So why the rush to impose further regulatory burdens on an already challenged industry?

Witter noted a public survey rolled out recently by regulatory reform advocates, which found that something like 86% of respondents in the EU wanted more environmentally safe chemicals.

"Yeah, of course," she said, "I can't believe it was only 86%. But what percentage of those were willing to change anything in terms of their behavior and their spending. Were they willing to lose out on something? To, you know, wash their clothes every fourth time they're worn, as opposed to maybe the two they're doing now?"

From Witter's standpoint, the whole conversation is disingenuous.

"There isn't a cupboard of new chemicals that we're just waiting for an opportunity to break out, this batch of amazing, high-functioning new chemicals that are unclassified, that meet all the regulatory requirements and are good to go," she said.

TiO2 Lessons

Witter pointed to the European Court of Justice's recent overturning of a hazard classification for titanium dioxide, *announced* on 23 November, as a potential rallying cry for disaffected chemicals industry stakeholders.

"What's really interesting is the methodology of the decision," Witter said. "So when the judgment came back, the problem that was thrown up in terms of the classification was that it wasn't solely an inherent hazard."

The Commission adopted a regulation in 2020 for harmonized classification and labelling of titanium dioxide as a substance suspected of being carcinogenic to humans, by inhalation, in powder form containing 1% or more of particles of a diameter equal to or below 10 µm. (Also see "*TiO2 Still A California Prop 65 Target; EU Commission Returns To SCCS With New Safety Questions*" - HBW Insight, 11 Oct, 2022.)

Witter went on, "This is something that is really the fundamental problem with things like endocrine disruptors, right? Because there is a science issue, if you like, in terms of whether that [endocrine activity] is an inherent hazard. … Endocrine disruption is a mode of action. It's not an inherent property in something."

Her advice to companies is at once to refrain from panic and possibly to go on the offensive.

"Sometimes it's best to hang back a little bit and see how some of these things unfold," she said. At the same time, "It depends on whether people are in groups and they want to actually start lobbying and pushing back on some of this stuff, because I do think it's going to be relentless over the coming years if people don't start saying, 'Actually we don't think this is manageable. We also don't think the science is that good.'"

She continued, "A lot of people get shouted down by, 'Oh, you're an environmental denier, you don't care about fish' and things like that." But no one's trying to pollute the environment, she said; rather, it's a matter of establishing workable policy based on sound science.

"Science is an ongoing endeavor, it's not an end point. There's no such thing as settled science. And I think that it is important if you don't agree with some of these things, or you think that there's some room for debate, to step into that space and start talking," Witter said. She added, "It's going to keep coming and keep coming if people aren't willing to stand up and say, 'I don't agree.'"

She pointed out that virtually every major EU regulation in recent years has ended up being stalled to some degree. "They rush these things out and then people are like, 'We can't do that,' and quite often it's the regulators or the central bodies themselves that can't manage because they don't have the capacity to do everything in that timeframe."

Witter advises companies, in addition to contemplating a lobbying strategy, to begin sketching out potential costs and devising a basic plan.

"There is a bit of sense in just taking a minute, taking a breath, and not being bounced into taking action. Take some time to see what the lay of the land is so you know what you're working with," she said.