Delivering a competitive EU chemical industry

THE COMPETITIVENESS OF THE EU COSMETICS, BIOCIDES AND PRESERVATIVES SECTORS

BRITISH CHAMBER OF COMMERCE | EU & BELGIUM

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Content

EXECUTIVE SUMMARY

This first in a planned series of British Chamber of Commerce in Belgium seminars and workshops on 'Delivering a Competitive EU chemicals Industry' brought together stakeholders from Industry, Member States and European Commission services to examine the competitiveness of the EU cosmetics, biocides and preservatives sectors. The aim of the workshops is to identify policy changes that can generate investment, innovation and business confidence in the EU chemicals sector.

The workshop heard presentations from the European Commission and Industry representatives outlining current procedures and issues around several interrelated regulatory packages including the EU's Regulations on the Classification, Labelling and Packaging (CLP), Biocidal Products (BPR) and Cosmetics. These regulations and their interplay are amongst issues currently under scrutiny in the fitness check of EU chemicals legislation (excluding REACH) being undertaken by the European Commission, the results of which will be known later in the year.

The chemicals regulation fitness check aims to identify excessive regulatory burden, overlaps or gaps in legislative scope, performance issues, regulatory inconsistencies and obsolescence, as well as what is working well.

Issues raised and debated included the relative expense and time involved for substance approval under BPR in the EU compared to other competitor global regions, the uncertainties involved in the regulatory processes and issues of capability in parts of the processes. All these factors hinder investment decisions in the EU for global companies. Loss of toxicology expertise was also an emerging issue.

Some studies show a serious lack of consistency in Member State interpretation and enforcement of chemicals regulations and this was having a negative impact on the competitiveness of the chemical industry in Europe. To predict the outcome of the approval process for any biocidal active substance with any degree of certainty is not possible. As Industry needed certainty to invest, investment decisions are on hold.

The potential impact of Brexit on the approval process for biocidal substances was also highlighted as many of the substance dossiers were handled by the UK. An appropriate post-Brexit mechanism is required to avoid further approval issues.

Greater engagement between applicants under BPR and the regulatory process was needed as well as easier access to available information on substances including possible read across of data from other global regulatory regimes.

Clearly, health, safety and environmental protection are paramount. However, the limited nature of the 'palette' of approved substances with effective preservative and/ or biocidal activity, and the widespread use of a small subset of this palette meant the potential for negative health impacts via consumer sensitisation and antimicrobial resistance was increasing, while approval of new active substances was slow. This could present a major future societal issue. An initiative by the cosmetics sector to understand real world exposure to these substances could be helpful here.

Substitution of substances is an alternative approach that can stimulate innovation and an initiative with the European Enterprise Network is helping SMEs find substitution solutions.

In general, continued engagement on these issues is required to support an efficient, coherent and competitive regulatory regime in the EU that delivers on its health and environmental protection objectives whilst sustaining industrial competitiveness.

Introduction

The British Chamber of Commerce in Belgium's EU Committee is planning to hold a series of seminars and workshops during 2018 on 'Delivering a Competitive EU chemicals industry'. The aim of the workshops is to identify policy changes that can generate investment, innovation and business confidence in the EU chemicals sector. This first expert workshop brought together stakeholders from Industry, Member States and European Commission services to examine the competitiveness of the EU cosmetics, biocides and preservatives sectors.

Supported by EUK Consulting, the workshop was chaired and moderated by **Tom Parker,** Vice-President of the British Chamber, who reminded the participants that the inspiration for the workshops had been a conversation with Lowri Evans, Director-General of the Commission's DG GROW, at a Chamber event in 2017.

Session 1

Chemicals Fitness Check: Purpose, Focus and Status

Kevin Flowers, Policy Officer for sustainable chemicals at DG Environment, kicked off the presentations with an overview of the current status of the Chemicals Legislation Fitness Check. As an initiative conducted under the Commission's Better Regulation programme, the primary objective of the Fitness Check is to assess the overall effectiveness, efficiency, relevance, coherence and EU added value of the framework of EU chemicals legislation (excluding REACH) against the core policy objectives of protecting human health and the environment and enhancing the single market and business competitiveness and innovation. The full results of the review were not yet available, but its scope covered all EU Chemicals Legislation except for REACH (apart from Persistent, Bioaccumulative and Toxic (PBT) substances), which was subject to its own review, pharmaceuticals and veterinary products and substance legislation relating to food or animal feedstock.

The EU's Classification, Labelling and Packaging (CLP) Regulation sets information requirements and obligations to identify, characterise, assess and classify chemical hazards. The CLP is aligned to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The review also included other chemicals-related legislation such as product specific regulations (cosmetics, plant protection products and biocides) and legislation covering effects on vulnerable populations and the environment. Having evolved over some 40 years, in total, some 200 regulations were encompassed within the review, but this had been narrowed down to 30-40 priority regulations.

Flowers described the EU chemicals acquis as using a careful mix of 'generic' risk management approaches and 'specific' risk assessment and management, as appropriate, based on exposure scenarios and hazard-based approaches to deliver effective Risk Management Measures (RMMs). Both approaches have their pros and cons, but the review sought to find if the balance was right and whether it is efficient, coherent and appropriate to achieve the core policy objectives including competitiveness.

The Fitness Check assesses the framework of EU chemicals legislation against five criteria - Effectiveness, Efficiency, Relevance, Coherence, and EU added value – with a view to identifying excessive regulatory burden, performance issues (with respect to its objectives), regulatory inconsistencies and obsolescence, and any regulatory gaps. This was clearly a complex area and a full quantification of costs and benefits was not feasible.

The process had started in 2016 with a deep dive into the legislation, a consultation exercise and collecting study data. A Commission Staff Working Document (SWD) is being drafted through Q1/Q2 2018 which is due to be reviewed by the Regulatory Scrutiny Board (RSB) in September before publication in late 2018. Any proposals for possible legislation and policy actions that may be needed would then follow in 2019 and thereafter.

Challenges and opportunities for Industry

Steve Smith, Senior Director, Global Registration and Regulatory Compliance, at SC Johnson described his company as a global market player with trusted consumer brands and a significant European presence with manufacturing facilities in the Netherlands, Poland and Ukraine. He compared the EU's Biocidal Products Regulation (BPR) with other global regulatory regimes. The US approach is less complex and more user friendly compared to the EU approach though the data requirements were almost the same for these and other OECD countries. However, the effort, costs and time to obtain approval and authorisation were considerably greater in the EU.

He then addressed specific challenges at the intersection between EU REACH, CLP and BPR regimes. A BPR review can trigger evaluation under REACH of non-active substances in a formulation and this led to data access challenges as often applicants were formulators and not actual substance manufacturers. One solution could be to harmonise assessment of non-active substances with REACH wherever possible and facilitate access to that data.

Another challenge is uncertainty when additional data may be requested by EU Member States for evaluating endocrine disrupting (ED) properties for non-active substances. According to the guidance, this should only occur when there are indications of ED properties based on the existing knowledge and the available scientific information. However, it is currently unclear what this means in practice. The European Chemicals Agency (ECHA) is developing an information system and a cooperation mechanism to assist evaluating bodies in Member States to decide on this issue. This system should be accessible for applicants to help them understand the status of ongoing evaluations and when/ if further data may be required.

In the case of human and environmental risk assessments, frequent application of the precautionary principle can drive uncertainty and additional safety factors with models, endpoints and RMMs taken in isolation. This compounding of safety factors and worst-case assumptions results in overly challenging risk assessment scenarios that do not relate to 'real world' situations.

Smith thought that there was a need to apply the 'innovation principle', get fuller engagement with enhanced stakeholder participation, including at Member State level, and ensure that decisions on key assessment parameters are not made on a piecemeal basis and that holistic impact assessments are performed prior to a decision to preserve realism and pragmatism. Could the OECD drive harmonised global approaches?

From a practical point of view, CLP often called for disproportionate labelling: a 100ml bottle of DEET repellent requires a label carrying approximately 650 words of text - 70 for CLP and over 550 for BPR compliance!

The ultimate call for Industry is: If you had EUR 300 000, would you invest in a BPR Product Dossier or a dossier for another country? Data requirements are shifting, interpretation between Member States varied and the whole process is long and unpredictable. The applicant is required to do much of the work carried out by governments in other countries (draft Summary of Product Characteristics (SPC), Product Assessment Report (PAR), study summaries and risk assessments) yet the fee is much higher and the time for review significantly longer in the EU.

Steve Smith proposed a way forward centring on the Mutual Recognition concept that balanced competitiveness and safety while aligning decision making and reducing the overall burden on all parties. This would require clear and consistent EU-level guidance to speed the process and clear, predictable EU-level data requirements. The evaluation procedures should both protect the consumer and work in line with market requirements (i.e. time and money).

Discussion Session 1

Tom Parker called for initial reactions to the first two presentations.

Federica De Gaetano of DG GROW asked for clarification on the statement by Steve Smith that the US and Canada did not require documentation on risk assessment for a product. Smith replied that though his company does conduct risk assessments US EPA does not require them to be submitted with the application, because the EPA conducts its own risk assessment. This, with applicant prepared PAR, SPC and study summaries under BPR, is a big difference between the EU and US regulations.

Mike Freemantle from Lonza noted that the issue was not the overall process for BPR that was problematic, but the 'nitty gritty'. "Hazard is a big problem – not the process," he said.

Kevin Flowers highlighted two aspects of the rationale for the fitness check: at EU agency level concerns had been expressed on improving the efficiency of the risk assessment process and in terms of implementation at Member State level there was a concern with available resources and capacity in some areas.

An Jamers of DG GROW insisted that the harmonised classification and labelling (CLH) process under CLP was a transparent process with numerous checkpoints in place. The difficulty often lies in the downstream legal consequences. **Mike Freemantle** replied that compared to other processes it is not transparent as there was no direct engagement with people doing the assessment work and other regions (US/ Canada) did not default to a precautionary worst case. The downstream issues had consequences in terms of how global companies considered their investment options.

An Jamers also observed that there were no representatives of DG SANTE at the workshop to discuss the BPR process; she indicated that

under the BPR there are possibilities for a product to be authorised based on socio-economic considerations even when it consists of, contains or generates a PBT substance (persistent, bio-accumulative, toxic). **Tim Kedwards** of SC Johnson thought that the regulations precluded innovation in the market.

Kevin Flowers said his understanding was that BPR now also allows for an EU-level authorisation of products (as well as the required EU-level authorisation of active ingredients), but was not used much – why was this? **Mike Freemantle** commented that every Member State had the right to comment on the assessment so just one country's objection could hold up the process.

Roberto Scazzola from the International Association for Soaps, Detergents and Maintenance products (AISE) was concerned about time to market. Are US colleagues not doing a good job since registration time of six months for an EPA registration (and another eight for State registration) is significantly shorter compared to about three years at EU level? Are we missing something? He noted that biocide regulations were not yet completely harmonised, and he felt that there was a need for a paradigm change with respect to products with a greater emphasis on benefits as well as hazard. He thought the fitness check on regulation was a brave idea and cited the case of labelling requirements for detergents that were currently covered by three different regulations. There was a clear need for improved coherence. **Kevin Flowers** agreed there was a need to recognise coherence issues and this would be addressed.

Linda-Jean Cockcroft of consultants Risk & Policy Analysts highlighted two points from studies relating to the fitness check. In the public consultation it was clear that respondents did not see a need for a change to CLP and the harmonisation process, but downstream legislation linked to CLP was seen to be an issue. She thought that the chances of opening 30-40 pieces of legislation were limited but she hoped that the fitness check would deal with the gaps in the current framework: the interaction between policy areas. She also commented that various studies have noted that the lack of consistency in Member State interpretation and enforcement of EU legislation has an important negative impact on the competitiveness of the chemical industry in Europe.

Federica De Gaetano underlined the need for a rigorous process to ensure the safety of ingredients and that this was a complex area.

Erwin Annys of the European Chemical Industry Council (Cefic) highlighted the potential impact of Brexit on the approval process for biocidal substances as many of the dossiers were handled by the UK. If there was no post-Brexit deal in this area, then he foresaw a major problem. He also had heard that compared to REACH the BPR process was less transparent and less open to interaction. He said that the process for harmonised classification (CLH) was crystal clear but not well known except to those directly involved. He stated that transparency in ECHA processes was clearly higher than in the European Food Safety Authority (EFSA) with respect to processes for pesticides. He was also concerned that so few companies fully understand the classification and labelling process outside of major companies.

Tom Parker asked how, or if, SMEs were able to interact with these processes? Was there a need for greater clarity around processes for application and evaluation? Is more or better information and guidance on EU websites required for Member States?

Kevin Flowers said that in the Fitness Check SWD there would be a large section on better regulation including analysis of effectiveness that stepped through the full process. He noted that ECHA produced a very large amount of useful guidance and felt there was a need to ensure a good balance in terms of information for maximum effectiveness.

Patrick Masscheleyn of Procter & Gamble (P&G) thought few people have full insight of the power (or not) of the tests required. In general, these tests had been formulated 40 years ago, before the era of animal-free testing. There was

an issue about relating older tests with newer guidelines and there was a need to use our experts to get consensus on areas of issue such as this. The new generation of toxicologists do not have experience of the older tests. This was a common challenge for Industry, government and academia, perhaps there was a role for the JRC here?

Aaron McLoughlin of Cefic agreed that experienced scientists were retiring. His experience of the process was that if sufficient, up to date data was submitted all goes well, but few individuals know the science that is needed and there was a clear skills gap on the horizon.

Tom Parker asked if the regulatory framework is keeping up with the science? In areas such as bioaccumulation is regulation keeping up with the science as it evolves?

Kevin Flowers stated that in the broad sense global bodies, such as OECD and the EU, ensure that testing processes keep up to date with issues such as endocrine disruption, neurotoxins and combination effects etc. He acknowledged that when substances are hazardous by their nature, as for biocides etc, then the risk management decision making process can become more complicated. In the fitness check the Commission was stepping back to see that its high-level objectives of protecting health and the environment were being achieved. He noted that a range of broad indicators (decreased sperm count, reducing insect populations etc.) could possibly be telling us that something else was going on. He reiterated that the fate of chemicals is important. Obviously, Industry is there to sell more product, but is it sustainable and safe? It is important not to lose sight of the big picture and the early warning signals.

Erwin Annys said that the role of OECD was extremely important. In terms of endocrine disrupting substances there was a need for validated methods; we should not make decisions using low quality methods. And validated new methods could be fast as demonstrated by existing 1st generation toxicity testing and skin sensitivity testing.

An Jamers indicated that information and guidance documents exist on CLP and the CLH process on ECHA's website and that national helpdesks have been set up that meet regularly together with ECHA in the context of Helpnet. She pointed out that while under the BPR, the requirement and initiative to submit a dossier lies with Industry, under CLP this typically lies with the Member State. Monitoring which substances are subject to a particular regulatory process at any given time may therefore be challenging under CLP, which could also explain the perceived lack of information or transparency under that Regulation.

Mike Freemantle stated that currently it was difficult to predict the outcome of the approval process for any substance with any degree of certainty and Industry needed certainty to invest. Internally there were always other investment options, for example, in pharmaceuticals where regulation was also rigorous, but the returns were much larger. The precautionary principle had increasing influence and it was now effectively a gamble for any new substance added to the regulatory process.

Roberto Scazzola agreed. CLP was fairly predictable, but for BPR predictability is very low and this leads to issues around investment. This was largely a resource issue as effectively only 3 or 4 countries were deciding for Europe.

Steve Smith commented on guidance. The US EPA regulation for pesticides (FIFRA or Federal Insecticide Fungicide and Rodenticide Act) dates from 1947 and guidance documents are still being written, it is not possible to anticipate all issues and situations that may arise. Other countries have already answered many of the questions raised here. Can we not analyse the best solutions and use their guidance and reviews? Even, perhaps, their data sets? The global standard for regulatory registration of biocidal products is 1-2 years, achieving this in the EU would bring it to the competitive place it needs to be.

Session 2

The important role of preservatives in cosmetics

Salvatore D'Acunto Head of Unit Health Technology and Cosmetics at DG GROW gave an opening presentation stating that the competitiveness of the chemical world goes hand in hand with the use of safe substances. Europe's cosmetics industry is the largest in the world, composed of over 4 600 SMEs, and the EU regulatory framework on cosmetic products is an inspiration for third countries. He felt the Cosmetics Regulation is solid with constant amendments taking place to the list of banned, restricted and authorised ingredients (i.e. annexes to the Regulation). The debate on preservatives used in cosmetics was crucial as they could only be used in the EU if they were authorised in Annex V of the Regulation, which currently lists 59 substances. Of these only a dozen are commonly used as preservatives in cosmetics, as well as being used across a range of end-use sectors. An extremely limited number of preservatives may lead to an increased risk of sensitisation for consumers.

The Scientific Committee for Consumer Safety (SCCS) is based in Luxembourg and is responsible for the risk assessment of preservatives while the cosmetics unit is responsible for drafting subsequent risk management measures to be discussed with Industry and Member States before their vote and adoption.

The importance of having a wide palette of appropriate preservatives to ensure the safety and quality of cosmetic products is a key challenge. There are currently on-going measures to restrict or ban some preservatives. Other current issues under discussion include preservatives that have been or may be classified soon as carcinogenic, mutagenic, or toxic for reproduction (CMR substances). In addition, interaction between CLP and the Cosmetics Regulation can be a tricky issue. The Commission has a legal opinion that a CMR classification of a substance does not lead to its automatic ban in cosmetics without a corresponding risk management measure. This is an extremely delicate issue with respect to the balance between consumer protection and consequences for the market. Currently some 200 substances used in cosmetics are classified as CMR and the Commission has drafted an encompassing act ("Omnibus Act") for their inclusion in Annexes II-VI of the Cosmetics Regulation. However, some Member States defend the idea of an automatic ban. Further discussions with Member States are ongoing.

On a more positive note, the Scientific Committee has recently approved a new preservative, the first for a while due to the difficulty for Industry to develop new preservatives in light of the animal testing ban and business uncertainty.

He reminded participants that two stakeholder brainstorming workshops had been organised by the Commission (DG GROW) in recent years on the preservatives issue. He felt that there is now clearer guidance on procedures and dossier submission for applicants and that deadlines were more stable. He thought that ad hoc meetings between applicants and the Scientific Committee could be possible in more complex cases. International cooperation through bodies such as the International Cooperation on Cosmetics Regulation (ICCR) is also important. This body has a working group on cosmetic product preservation that is drafting a white paper on why it is important to have a wide palette of cosmetic preservative ingredients.

Investing in the future

Phil Hindley, Head of Global Marketing for Preservation and Laundry at Lonza then presented on innovation in preservatives. He noted that preservatives were a largely unseen and unconsidered part of a formulation – unless they did not work. The personal care industry in particular has a wide range of options available to it that can offer some element of preservation effect in a finished product (although many of these (aka multi-functionals) are not classified and regulated as preservatives), however regulatory and consumer pressure was reducing the available 'palette of preservatives' leading to diverse sectors relying on a small core of preservatives and consequently increasing total consumer exposure to these substances.

Since 2017 Lonza had developed a new approach to the consumer-facing preservation markets that aims to be balanced and as future proof as possible. There are three components to the approach: Defend existing, well-used and trusted products including some that the market may consider as 'controversial'; Develop – an extension of defend by making more of the Industry's existing portfolio of substances through formulation expertise and combination approaches; and, Innovate – creating new market offers, all targeted at providing greater choice and flexibility for formulators and consumers.

The innovation component covered three areas: Potentiators able to boost the preservative action of other substances; Multi-functionals that had a preservative effect although that was not their primary purpose in a formulation and therefore they were not classified as a preservative per se; and, new Preservation Actives which was the main investment area, and where Lonza felt they could make a difference.

Hindley noted that innovation should not just be constrained by R&D, and that each innovation needed to be carefully positioned: focused on the best market fit, target end-product or end-application, likely use pattern and exposure etc. He saw the innovation 'space to win' as sitting between the regulatory framework and market demands.

This presentation was followed by **Patrick Masscheleyn** of P&G who focused on the socio-economic contribution of the European cosmetic industry and the need to maintain a palette of preservatives as margins of safety will become lower for the remaining preservatives. One thing was clear: if society did not have access to effective preservatives then society would have a significant health problem. Perhaps a "deprivation test" was required.

Masscheleyn advocated a holistic strategy that affirmed all preservatives currently in Annex V of the Cosmetic Products Regulations and allowed for new additions. Cosmetics Europe had launched a Product Preservation Programme and Preservatives Protection Project that included a survey to establish exposure data using trustworthy sources of fully validated data. This was an essential exercise to better understand the volume and distribution of preservative exposure due to cosmetics. It will be an important aspect for keeping a wide palette of

preservatives to ensure product and consumer safety and assist in addressing environmental safety aspects under REACH.

He outlined the challenges. A hazard-based CLP needed to be managed well to avoid a domino effect that can lead to loss of safe preservatives and regrettable substitution choices. We needed to step back and remember that preservatives are designed to kill microorganisms. He was also concerned that there was a lack of accepted animal-free tests for several toxicological endpoints which are important to establish the safety of cosmetic ingredients.

Probabilistic risk assessment and other novel risk assessment techniques needed to be adopted by regulatory bodies to support a holistic management of the palette. Such holistic management could go beyond the chemistry to include other EU policy aspects including single use packaging and improved recyclability amongst other issues.

Helping Industry with substitution

The final presentation came from **Timoteo de la Fuente** of DG GROW and covered the concept of substance substitution. Substitution can help Industry competitiveness and is encouraged not only for reasons around health and environmental protection issues but also to stimulate innovation and reduce regulatory compliance and other costs. Substitution may also be driven by market demand and often reasons to substitute go beyond regulatory issues. Substitution can involve the direct replacement of one substance by another substance but also new processes or product designs.

He described the Enterprise Europe Network (EEN) project that is working with some 600 institutions to help build capacity within smaller companies in terms of substitution. There was ongoing work with the European Agency for SMEs (EASME) Partnership Opportunities Database (POD) to see how that could be used to establish contact between SMEs potentially interested in substitution through analysis of POD company profiles. The idea was to bring together SMEs interested in replacing substances of potential concern and solution providers and several guidelines for POD users had been developed to facilitate dialogue.

A pilot project had been completed and a second phase was about to commence. The project was helping SMEs to reduce search costs for alternative solutions to selected hazardous chemicals, was accelerating substitution, creating new markets for biobased substances, and improving the recyclability of products. DG SANTE was also looking to extend the POD approach to biocides.

Discussion Session 2

In the final discussion session **Tom Parker** again asked for reactions and input.

Patrick Masscheleyn emphasised the critical importance of maintaining the palette for preservatives. In order to achieve this, it required more details about exposure, risk assessment and decision-making and this was why the Cosmetics Europe user survey was so important. The ultimate goal was to use the information to determine true exposure. If we have no data then we must be conservative in assessment, but if we have the data we should use it.

Federica de Gaetano commented that any risk assessment must be based on the dossier that in the majority of the cases for cosmetics is received from Industry and the more robust the dossier, the better the risk assessment. In terms of exposure there was a need for data to assess aggregate exposure and we need to know what is being used. Experts involved in the risk assessments may not be experts on preservatives and their effectiveness; this aspect should be covered by the manufacturer of cosmetic products through an open dialogue between SCCS experts and Industry.
She also asked for clarification on multifunctional substances listed in the CosIng (EU) database and how they related to the list of '59 preservatives'. **Phil Hindley** said these were substances not on the Annex V positive list of preservatives, but that they were widely used in Industry. They had a specific primary function, for example a humectant, but also had an observed secondary function as an antimicrobial. Guidance allows responsible use of such substances by Industry. Obviously a 'true' regulated preservative, designed for purpose, would typically be more active than a multifunctional substance.

Tim Kedwards of SC Johnson applauded the approach by the cosmetics sector and the survey to characterise exposure through understanding actual use but thought there was a need to en sure Member State colleagues were involved with or aware of the initiative.

Mike Freemantle commented that, from a biocides perspective, data on the volume used according to regulation seemed to indicate that there were massively more sales than was actually used so this could be a much better scientific approach.

Patrick Masscheleyn warned that if we don't master the science we will default to a conservative view, which was not good for competitiveness. In response to a comment that Industry is here to sell more products despite questions about their safety, he emphasised that it was his duty is to make sure products are safe - after all he recommends them to his own family. Good products are profitable products. He felt that it would be useful to park the difficult scientific questions and work to solve them together. The US EPA has firm links with policy makers and the science community and for key questions it brings experts together to review the issue.

Kevin Flowers reiterated the critical need for robustness of exposure assessment. It was important to get the science and the data on the table to allow accurate risk assessment; however, this would involve a trade-off against time, resources and efficiency. He welcomed the initiative to improve knowledge in the cosmetics industry but noted that the average consumer would have next to no understanding of biocides in cosmetics. However, the closer we can get to this knowledge, the better. He also thought reality checking assumptions during risk assessment was important – are we assessing against real life? He noted that feedback monitoring of risk assessment outcomes was not good.

Petra Leroy Čadová from DG GROW agreed that a holistic approach to the risk assessment of preservatives used in cosmetic products could be effective rather than the current 'case-by-case' approach. Picking up on a previous point, she wondered how such a holistic approach might be implemented and who would

carry out the impact assessment as suggested by Steve Smith.

Roberto Scazzola commented that for substances in cosmetics the nature of exposure was quite different compared to other application areas and sectors. There was a need to consider the availability of specific products, no one has exclusive ownership of the benefit of biocides.

In his closing remarks, **Salvatore D'Acunto** applauded the open dialogue reflected by the British Chamber workshop. He appreciated that Industry has changed its attitude but insisted that substance dossier must be exhaustive and precise. He indicated that he had taken on board the positive discussion with respect to aggregate exposure and felt that the SCCS had already shown openness with respect to dialogue on such issues and was open to differentiated approaches.

Resolution of the issues raised in the workshop would not be achievable overnight, but the signs were clear and encouraging. It might take some time, but the signals were encouraging that a different scientific approach could be achieved at EU level. However, there would likely remain different perceptions and approaches at Member State level.

Conclusion

Tom Parker thanked all participants to the workshop and looked forward to a continuing and constructive conversation in this area.

SPEAKERS

This was the first in a series of seminars that the EU Committee plans to hold in 2018 on 'Delivering a Competitive EU Chemicals Industry'. The purpose was to identify policy changes, which can generate investment, innovation and business confidence in the EU chemicals sector.

Moderator:
Tom Parker, Vice-President, British Chamber of Commerce | EU & Belgium

Speakers:
Kevin Flowers, Policy Officer for chemicals in particular implementation of 7th EAP, Unit B2, DG Environment, European Commission "Chemicals Fitness Check: purpose, focus and status"

Steve Smith, Senior Director, Global Registration and Regulatory Compliance, SC Johnson "Challenges and opportunities for Industry "

Salvatore D'Acunto, Head of Unit, Health Technology and Cosmetics, DG GROW, European Commission "The important role of preservatives in cosmetics"

Phil Hindley, Head of Global Marketing for Preservation and Laundry, Lonza AG "Investing in the future of preservatives"

Patrick Masscheleyn, Vice President, Research & Development, Global Product Stewardship, Procter & Gamble "Investing in the future of preservatives"

Timoteo de la Fuente, Policy Officer, Unit D2, Chemicals, DG GROW, European Commission "Helping Industry with substitution"

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