

CTPA'S RESPONSE TO THE UK PRODUCT SAFETY REVIEW CONSULTATION (OPSS, October 2023)

Summary Position of CTPA towards the PSR Consultation

The UK cosmetics industry considers the UK Cosmetics Regulation (UKCR)¹ meets the objectives of ensuring consumer safety, supporting businesses through compliance, fostering innovation and promoting growth through domestic and international trade. CTPA would like to request the Office for Product Safety and Standards (OPSS) to recognise what works, preserving the UKCR and the high standards reflected therein.

While CTPA does not support the inclusion of the UKCR within the proposed horizontal framework, we align with the efforts from OPSS to improve and future-proof regulation for consumer goods.

The UK cosmetics industry should be able to leverage the use of new technologies and scientific advancements, which may present the opportunity to make a significant contribution to society, including in the way in which consumers interact with daily and essential products.

Promoting the role and leadership of OPSS remains important to ensure a co-ordinated approach to regulation and enforcement, but this should be in close partnership with local authorities and businesses.

Introduction

The cosmetics and personal care sector in the UK

Cosmetic and personal care products are an essential part of the day-to-day lives of the people in the UK, contributing to their wellbeing and self-esteem.

Representing all types of companies involved in making, supplying, and selling cosmetic and personal care products in the UK, the Cosmetic, Toiletry and Perfumery Association (CTPA) acts as the voice for a vibrant UK industry. CTPA's goal is to enable the cosmetics and personal care industry to deliver excellence and support wellbeing.

The cosmetics industry and personal care sector is an £8.94b industry (CTPA Annual Report, 2022), and continues to evidence growth in the recovery process from the economic decline surrounding the COVID-19 pandemic. CTPA's membership encompasses over 230 individual businesses, distributed across all the UK, including all devolved nations. Represented are companies of all sizes, from small pioneering businesses to large multinationals with significant expertise in the UK.

International trade plays a significant role for the cosmetics and personal care industry, where UK products are shipped around the globe to the value of £3.9b in 2022 (CTPA Annual Report, 2022). The UK's main trading partner remains the EU accounting for 64.7% of all exports. Outside of the EU, countries such as United States, United Arab Emirates, China, and Australia are examples of countries where UK brands continue to benefit from trade opportunities.

From fostering future talent to contributing a science-led perspective on emerging issues, CTPA is proud to champion the UK cosmetics and personal care industry. CTPA supports members and the wider industry by providing in-depth education, training, and guidance on the scientific and legal requirements for placing

¹ Regulation (EC) No 1223/2009 on Cosmetic Products, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

cosmetic products in the UK. We support industry best practice and cooperate with the UK government in the promotion of the industry, both within the UK and to the world. CTPA's Sustainability Strategy unites members and the wider industry in the journey to becoming net positive, supporting the UK Government climate ambitions.

Consumers remain at the heart of the cosmetics and personal care industry. CTPA's 'More than a Feeling' report highlighted the role that our products play in society, where using toiletries for cleanliness was valued as a key factor in self-esteem by 84% of UK's adults. In fact, 85% of UK adults class cosmetics and personal care products as essential to their lives. This figure grows to 94% among women. The UK cosmetics and personal care industry provides safe and effective products to UK consumers, making a big difference even with the smallest of products. ²

Summary of CTPA's response to the Product Safety Review Call for Evidence

CTPA supported the need for the strong rules currently in place through the UKCR to regulate cosmetic products.

In response to the Product Safety Review call for evidence launched in 2021, CTPA stated how the current regulatory framework for cosmetic products, the UKCR ensures product safety while allowing companies to maintain growth and innovation. The cosmetics industry maintained that the UKCR combines comprehensive risk-management with a deep understanding of the particularities of the products that fall under the legal definition of a cosmetic product.

CTPA shared ideas on how to further reinforce the already effective regulatory framework, including a more active engagement with consumers to promote their trust, areas in which further guidance could help SMEs better understand their requirements, and ensuring that the regulation continues to be relevant in light of new technologies and consumer habits.

Ensuring the safety of products has always been paramount to the cosmetics industry, and this was reflected in CTPA's response to the call for evidence, where CTPA suggested guidance to help businesses understand all their legal obligations. However, the use of guidance or voluntary standards to meet safety requirements was opposed by CTPA. Additionally, CTPA proposed that alongside the increased support to industry and consumers, enforcement authorities should also receive sufficient coordination and support to promote their work of market surveillance and consumer protection.

² Opinium research for CTPA. Conducted 25.02.22 – 01.03-22 on nationally representative sample of 2000 UK adults.

Product Safety Review Consultation

The current regulatory framework

CTPA understands that there are no urgent or significant areas for improvement for the UKCR that require immediate regulatory change.

Following the entry into force of the UKCR, CTPA has been providing the support and perspectives of the cosmetics industry through the process of implementation and application of the UK regulatory framework. Through this cooperative effort, CTPA was able to proactively raise a number of issues, such as finalisation of the process for ingredient management (especially for ingredients classed as CMR under GB CLP), and the development and improvement of the Submit Cosmetic Product Notification (SCPN Portal). OPSS have partnered with CTPA and its members to reach a resolution to these matters.

During the initial stages of the UK Government's proposal to repeal all retained EU legislation through the introduction of the Retained EU Law (Revocation and Reform) Bill 2023 (now the corresponding Act), CTPA explored repeatedly with members the opportunity to introduce amendments or changes that would simplify the operation of the UKCR. No areas concerning the way in which cosmetic products are regulated were considered as burdensome, disproportionate, barriers to innovation, or impeding the ability for companies to place cosmetic products on the market.

Complementing the collaboration with OPSS, CTPA continues to support the UK cosmetics industry through the development of assured advice, exploring the legal interpretation of the UKCR, through the Coordinated Primary Authority Partnership with Trading Standards.

Vision for a future framework and bringing products to market.

The cosmetics industry remains committed to placing safe and effective products across the whole of the UK market, including Northern Ireland, and believes that the current vertical framework, the UKCR is already a proportionate way to achieve this objective and meet the expectations of every UK consumer.

The PSR consultation introduces OPSS's aim to "bring together retained EU law and domestic legislation into a single, coherent framework". CTPA understands that such an approach would be in direct contradiction to the response provided on behalf of the cosmetics industry to the call for evidence preceding the launch of the consultation and would like to take the opportunity to expand on the challenges presented if such an approach were to be introduced for the cosmetics sector.

CTPA is aligned with the expressed goal from OPSS to ensure that regulation is proportionate, agile, and supportive of UK business' growth and innovation. The UK cosmetics industry strongly believes the UKCR to be an example of smart regulation: one that is simple, coherent and has consumer safety at its core while also helping to grow the economy.

On the competitiveness of the UK Cosmetics industry

The UKCR sets globally recognised high standards in place, allowing the cosmetics industry to focus on investment and innovation.

Supporting innovation is key for a sector such as the cosmetics industry, where companies are directly meeting consumer expectations, creating and following market trends and where culture, social development and people's daily lives directly influence the products that are available. The UKCR is a framework that allows for innovation, enabling businesses to grow and invest. Examples of this innovation can be seen in personalised cosmetic products or packaging design, which allow consumers to benefit not

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just from an improved experience but also factor in inclusive and accessible practices; developments in sustainable packaging options to promote the UK's climate objectives; and the scientific development of validated *in vitro* and *in silico* testing methodologies for safety and efficacy outcomes.

A source of concern for CTPA is that the proposed horizontal framework would focus innovation on efforts to reduce potential harms (hazards, not real risk) to allow for a simpler classification or reduction on the regulatory burden associated with the decision to include certain ingredients or manufacture certain product types. To an industry like cosmetics and personal care, this approach would actually reduce innovation, whereby resources are put into lowering a product hazard classification, and not into developing products able to meet consumer needs in the same way. This will directly reduce consumer choice. For example, avoiding a safe ingredient with a hazard potential, such as the toothpaste ingredient hydrogen peroxide or the sun protection ingredient titanium dioxide, may lead to a reduction of product performance. This is especially concerning for products with crucial health benefits. This may also apply across whole product categories, for example products intended for children or babies. The potential hazard may determine that safe products are not placed on the market due to additional or burdensome requirements. This would directly affect the competitiveness of the UK cosmetics industry, without improving safety to the consumer. The existing framework ensures safety of cosmetic products in the UK, and companies can rightly focus innovation on a direct consumer benefit.

The current regulatory framework for cosmetic products is based on what is considered globally as a gold standard in the regulation of our products. This approach has been adopted in many other areas, such as ASEAN countries, and has greatly influenced other territories such as the GCC and other Middle Eastern countries. For territories like Australia, New Zealand, and partners of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), cosmetics are included in Free Trade Agreements with the understanding that keeping close collaboration will promote trade and benefit UK businesses. The value of UK cosmetic and personal care exports in 2022 was £3.8billion, a figure supported by the recognition of the quality of UK products and the reassurance of safety provided by our regulatory framework. Over 70% of those exports are to territories that share a common regulatory framework, with the ability to secure the trust from foreign regulators through documents such as the Certificate of Free Sale, which mentions a legislation authorities can trust.

Additionally, the UK internal market would be at a greater risk of fragmentation. Under the current arrangement with the EU, the Windsor Framework, cosmetic products placed on the market in Northern Ireland must conform with different rules to those products placed on the market in Great Britain. Existing supply chains already account for the existing differences between Great Britain and Northern Ireland. It must be recognised that the proposed horizontal framework challenges the compatibility of these requirements and places additional burden on UK companies to ensure they are able to meet the expectations of all consumers, no matter where in the UK they are located.

Changing the way in which our products are regulated will certainly cause a reduction in the competitiveness of UK brands in the global market. The need to adapt and learn a new model will shift the focus of companies from growth to understanding and implementing new requirements. The introduction of incompatibility with global markets could make it harder for companies to place their products on the market abroad, as they may need to make substantial changes to their products to comply with regulatory requirements. Furthermore, consumer perception of the safety of UK products may shift to a perception of lower regulatory scrutiny (a perception that UK consumers may already have towards many imported products).

A shift to the responsibility being on the importer to conduct the assessment of hazard and thus establish their compliance requirements, could lead to cosmetics imported into the UK from third countries not upholding the safety standards which exist today. This would result in more unsafe products being made available on the market to UK consumers. Furthermore, the notion of presumption of conformity is

mentioned in the proposal, which contrasts with the UKCR today under which the obligation to be able to demonstrate safety of cosmetic products lies with the Responsible Person.

While there is currently only limited or anecdotal evidence that cosmetic companies are unable to understand their regulatory requirements, there is plenty of evidence that the UKCR is working for all stakeholders involved in placing cosmetic products on the market. Introducing a new approach and reviewing the current rules in place for cosmetic products will bring uncertainty, potential disruptions to the supply of products to UK consumers and will increase the burden to industry rather than reduce it.

On hazard-based legislation and a cross-cutting approach

When considering product safety, decision-making and policy-making regulators must consider factors such as exposure and benefits to the consumer, rather than simply intrinsic hazard properties. Hazard does not mean actual risk.

CTPA has continuously supported the merits of the current risk-based regulatory framework that promotes robust safety principles and sound science. This approach has been implemented in the UK for over 10 years and has a demonstrated track record of allowing companies to place safe and effective products on the market.

It should be noted that clear definitions and understanding of ‘hazard’ and ‘risk’ should be provided alongside the proposal. While these terms are generally accepted, they are often incorrectly used interchangeably or in a way which could lead to misunderstanding of how they might be operating at a regulatory level.

The current UKCR includes risk-management tools to effectively manage the specific hazards that cosmetic ingredients and products may pose. This allows companies to examine the safety of cosmetic products in their correct context (use of ingredients within a formulation, exposure, target consumers, method of use, etc.), and to ensure that a safety decision is made based on robust exposure-led approaches, taking all these factors into account. Legislation should reflect real consumer risk and establish the requirements and mechanisms to ensure safety based on those risks identified.

The framework proposed in the consultation intends to introduce hazard-based legislation. While there is clear indication that risk-based requirements would be put in place to ensure consumer safety, the cosmetics industry is concerned that this proposal would greatly reduce the safety standards for cosmetic products placed on the GB market. The proposal does not take into account the specific and detailed requirements of ensuring cosmetic product safety from a consumer-use perspective. Risk characterisation is key to assessing the safety of a product. The cosmetics industry strongly opposes a change in approach whereby potential harm (hazard) supersedes risk in decision-making. For example, a standard cleansing product such as a hand wash will contain surfactants to deliver the product benefit. Surfactants may have intrinsic hazardous properties when taken in isolation, but when used diluted, in combination with other ingredients and under correct use, products containing surfactants are not only safe but contribute a great societal benefit.

CTPA’s concern with a hazard-based approach lies also with the fact such a proposal may only be effective at capturing potential, unspecific harm to consumers and have a lesser degree of consideration to the foreseeable or normal use of the product. This could lead to the overly burdensome principle of avoidance of worst possible harms, rather than the pragmatic assurance of safety in use.

It must be noted that the proposal does give consideration to risk-based safety requirements and the need to conduct a classification or categorisation exercise to assign products to tiers or degrees of hazard and the consequent risks. This classification would determine the requirements to bring products to consumers. However, this may introduce an unclear path to market which would go against the objective of reducing complexity and compliance costs. These steps are simplified in risk-based legislation, such as the UKCR,

where the common potential hazards across a product type have been identified and the safety requirements have already been determined. CTPA is concerned that such an approach will remove the level playing field that companies currently operate to, and reduce the safety of products on the market, as different companies will approach the evaluation using different methods and to differing levels of detail. The current UKCR already provides a common approach.

In understanding product safety as establishing a mechanism of both exposure and hazard, we must give thought to how this may be determined. Evaluating product safety in hazard terms will result in a tiered approach or 'traffic-light' system, but a hazard-based framework would be unlikely to give risk the weight it merits in safety, and it is risk that should be at the centre of the regulatory proposal. A higher hazard profile would also determine greater administrative requirements to placing the product on the market, and this may be the case even where the risk of the product may have been effectively managed, resulting in additional burden without a real contribution to safety.

Further, imposing safety and transparency and communication requirements would of course be a needed follow-up to the hazard or risk classification, but these are already clearly and effectively set out in the current UKCR. An assessment of safety based on hazard, which determines subsequent compliance requirements brings the possibility of CLP-like labelling for cosmetic products. Under the UKCR, cosmetics are labelled according to the risk they pose under normally foreseeable conditions and are fully exempt from hazard labelling requirements under CLP. Hazard labelling is not suitable for cosmetic products as it does not communicate real risk to the consumer and would result on labelling being inconsistent across different products creating great confusion among consumers. These labelling requirements are far from international best practice for cosmetic products, meaning that UK consumers would be significantly disadvantaged and directly affecting the ability for UK products to enter global markets.

CTPA does understand the merits of the proposal to define common approaches to common hazards or risk posed by products that may be used in a similar way, in a similar environment or by the same target consumer. Equally, we can also support the idea that products that pose a greater risk to consumers may need increased supervision to ensure consumer safety. However, these principles are already operating effectively within the UKCR, and any alteration of the existing approach puts safety at risk.

On the need for product-specific regulations

Sector-specific legislation enables industry to clearly understand their legal responsibilities on product safety, provides a clear relationship with the broader legislative landscape outside of OPSS, supports the current animal testing ban for cosmetic ingredients and products, and reassures consumers that UK cosmetic products remain safe.

As a trade association, CTPA is committed to providing in-depth guidance and information to our members and the wider industry on the regulatory framework for our products. CTPA has supported OPSS with the creation of detailed guidance, educational resources for big and small companies, and has promoted the importance of safe products across the industry. CTPA is in a unique position to understand not just where the complexities lie, but where companies may have a harder time understanding the requirements in the current legislation. This informed CTPA's submission to the Product Safety Review call for evidence.

Cosmetic products are an outlier amongst the majority of consumer goods under regulatory supervision by OPSS, designed to be used in contact with consumer's skin, and thus require a more comprehensive risk assessment. The industry does not support grouping cosmetic products in a regulatory framework with other consumer products with very different usages as it will compromise consumer safety and innovation.

Product-specific legislation has the advantage of ensuring product classification remains the key first step in a company's compliance assessment. Product classification determines the regulatory objectives and safety

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requirements and remains a simpler exercise than a complete hazard and risk assessment. For example, a moisturising cream with no therapeutic claims would be classified as a cosmetic product according to the definition within the UKCR. For this product, the UKCR then defines any ingredient restrictions and prohibitions, information and documentation requirements, labelling obligations and consumer protection provisions, as well as the need for a safety assessment. These requirements are well established, tested and familiar to industry. There is only a very limited pool of 'borderline' products where classification may not be as straightforward, and in these instances industry and regulators can draw on a wealth of joint experience and existing guidance to support this process.

Classification of a product according to a definition is likely to be easier and less time consuming than classification according to an assessment of its potential harm. This method of classification is commonly used globally, with many countries having adopted the same or a similar definition for 'cosmetic' as under the UKCR. A further consequence of classification by potential harm is the increase in difficulty posed by the differing requirements across the same product type or even similar products. For example, a moisturising cream may be regarded as low risk, but the addition of a hazardous ingredient within an established safe limit, such as a very low concentration of sodium hydroxide as a pH adjuster, may still result in a higher level of classification and the placement of undue requirements, with no benefits to consumer safety.

Cosmetic ingredients are already well regulated in the UK through the annexes to the UKCR, leveraging the existence of an independent committee (SAG-CS) to protect consumers and provide clarity to industry. The process of regulating ingredients, while it may seem intensive, reassures consumers on the safety of their cosmetic products and provides industry with the following benefits: a consistent approach to the review of the safety of ingredients that may be used in cosmetic products; independent scientific assessment on the safe use of these ingredients specifically in cosmetic products; legal certainty regarding the status and transitional arrangements made to phase out any ingredient deemed unsafe to allow industry sufficient time to reformulate. Consumers are presented with an additional level of trust, knowing that cosmetic products do not contain harmful substances such as those listed in Annex II of the UKCR. The current UKCR already ensures a systematic and continuous updating scheme on effectively regulating ingredients.

The legislative approach to ingredient management may introduce challenges from a governmental administration point of view, but it also ensures that industry is involved in the assessment of any proposed restriction and that opportunities are given for industry to provide data to support the safe use of ingredients. The current ingredient management process under the UKCR allows for sufficient sight of the pipeline of ingredients for review, which in turn would allow for periodical updates to be introduced as opposed to individual ingredient changes. Grouping the legislative process of ingredient management, such as that it would only need to be undertaken once a year for example, would only require a change in policy and not legislation.

Emergencies surrounding cosmetic products or ingredients that require immediate attention can be considered extremely rare, and provisions exist within the current framework to allow for the proportional action to be taken efficiently. The UKCR determines that only safe products may be placed on the market; in the event of an extremely serious and justified concern regarding the safety of products or ingredients, industry is obligated to work with OPSS to take appropriate proportional steps and ensure consumer safety.

Sector-specific legislation also allows for consideration of legislation outside of the scope of the remit of OPSS, such as GB CLP³ and UK REACH⁴. While cosmetics are under the scope of the UKCR, individual ingredients

³ European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 No. 720 and by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020

⁴ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EUR 2006/1907) as amended by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

and mixtures (excluding finished goods) are regulated under the chemical frameworks. Provisions within the UKCR allow for the possibility that these legislations may limit the use of ingredients in cosmetics on the basis of considerations other than consumer safety, or without consideration to the consumer exposure of the end product. These provisions allow industry to submit evidence of the safe use of ingredients, and if found safe in the context of cosmetic products, maintain the choice for companies to continue to formulate using these substances. Changes to the current process could lead to unnecessary restrictions on such ingredients being imposed, impacting product innovation at no additional benefit for consumer safety.

A clear example of the interaction between regulations can be found in the substance methyl salicylate. This substance has received a mandatory classification under GB CLP as a CMR substance (carcinogenic, mutagenic, or toxic for reproduction). This classification however does not immediately mean that the substance is unsafe, because a CMR classification is a hazard classification and represents the worst-case properties of a substance, rather than its properties as used at a low concentration in a consumer product. Although CMR substances are banned for use in cosmetic products under the UKCR, it also allows industry to meet the exemption criteria for continued safe use. OPSS is therefore conducting an assessment of the substance to determine the safety of its use in cosmetic products, allowing industry to present evidence to the fact. In cases such as these, a significant hazard is taken into consideration and evaluated in context to determine how the ingredient can be safely used in cosmetic products. Under a hazard-based approach it could be hard to justify the safety of the ingredient within a product, as each individual company would have to be in a position to determine ingredient and product safety; which now takes a concerted industry effort due to the required expertise, complexity and cost of data generation. In addition, different companies may take different approaches which would not provide the same level of reassurance to consumers that currently exists with the independent scientific assessment process for CMR substances. This in turn would be impossible without the clear links and legal requirements established in sector-specific legislation.

The UKCR regulates product and consumer safety also in light of ethical considerations for industry, science and consumers. The introduction of the animal testing ban in the UKCR ensures that these principles are strictly applied within the UK, promoting the development and investment in New Approach Methodologies (NAMs) and furthering their application within the context of consumer safety by enabling decision-making without the need to generate data in animals. However, the Next Generation Risk Assessment (NGRA) techniques used to ensure consumer safety developed over the last 10 years are risk-based and exposure-led as described by the International Cooperation on Cosmetic Regulation⁵. Whilst there are early discussions on the use of NAMs for hazard-only decisions, these are nowhere as mature as the science developed over the past 20 years for consumer safety assurances, as acknowledged in the 2023 revision of the SCCS Notes of Guidance in the EU, which remain relevant to OPSS.

On the balance between regulation and guidance/standards

Guidance and standards are a complement to legislation, but they do not offer clarity and certainty to industry, reduces transparency, compromises the effectiveness of enforcement, and risks placing additional burdens on industry.

It is well noted in the consultation proposal that, even if currently there is a large volume of legislation, industry remains familiar with the current framework and requirements. The cosmetics industry is currently able to rely on a small number of regulations which establish clear obligatory requirements for placing products on the market. These rules are supplemented by UK Government guidance, as well as industry guidance and best practice developed both in the UK and abroad in jurisdictions with comparable regulatory frameworks. Standards supplement legislation and guidance, either by representing an acceptable standard

⁵ <https://www.iccr-cosmetics.org/>, Alternatives to animal testing.

of compliance (such as designated standards) or by ensuring common and scientific approaches to compliance, such as microbiological or SPF determination standards.

A potential move towards greater or total reliance on guidance and standards increases the risk of uncertainty of interpretation and compliance, alongside an additional resource and cost implications. The creation of guidance does not provide the same level of scrutiny and transparency as legislative changes. Cosmetic product safety would be impossible to manage with the current existing standards as adopted under the British Standards Institute (BSI). Additionally, standard development is a lengthy process; with ISO standards taking on average three years to develop.⁶

The cosmetics industry has a thorough understanding of the legal requirements for placing cosmetic and personal care products on the market, which is evidenced through a long-standing track-record of safety. CTPA and the cosmetics industry continue to support the need for clear legal rules, providing a level of assurance and certainty to consumers, businesses, and other global regulators that guidance is unable to provide. UK Government guidance might have limited enforceability, and the possibility of quick change without due scrutiny or a transparent process may increase uncertainty for businesses, if not in reality at least at the times where decisions must be taken. Industry-led guidance is currently useful to clarify legal requirements and encourage global best practice, but industry should not self-regulate with regards to safety. This would not only create an uneven playing field for industry and compromise the safety baselines and principles we now hold, but it may even contribute to the appearance of more enforcement-by-lawsuit approaches which we see in other jurisdictions. In many cases, these legal actions cannot even be called real consumer protection and redress, let alone be a measure for safety.

The UKCR requires all products to be safe and establishes clear roles and responsibilities within the regulation to ensure this outcome is met. The 'Responsible Person' (RP) is the figure ultimately accountable for product safety and legal compliance. This burden lies clearly with industry, but the UKCR also establishes the minimum requirements for all RPs to meet and is able to place regulatory measures to intervene on matters such as ingredients. This balance allows for a joint market supervision, with a responsible and proactive industry that can innovate having the reassurance of meeting minimum industry requirements, and OPSS (with Trading Standards) taking action against unlawful and irresponsible businesses having established a level playing field. CTPA is concerned that under a common hazard-based framework, there would not be a clear basis to take enforcement action against companies selling unsafe products, making enforcement more difficult.

A shift to a guidance and standards-based approach is likely to also increase the burden and cost to businesses directly. We may consider an existing example to understand this: the legal requirement to ensure Good Manufacturing Practices, related to the quality and safety of manufactured goods.

Currently the UK cosmetics industry can rely on a designated standard to demonstrate compliance with Good Manufacturing Practices. The adopted international standard BS EN ISO 22716 has been available and widely used by industry in the UK and abroad to demonstrate compliance with this key quality and safety-related requirement. Even though other standards are available, and companies can demonstrate compliance through individually developed standards, a high proportion of the industry has chosen to make use of the designated standards to ensure they are comfortably within compliance of the regulation.

The implementation of this designated standard has been widely accepted by the cosmetics industry, but implementation and use of standards is a resource-intensive exercise. CTPA members companies have reported that ensuring compliance with ISO 22716 in manufacturing facilities will require usually at least one full-time employee for medium sized businesses, and full teams within multinational companies with more

⁶ <https://www.iso.org/developing-standards.html#:~:text=From%20first%20proposal%20to%20final,place%20somewhere%20in%20the%20world.>

than one manufacturing site. For small businesses, or those who do not have manufacturing facilities, but which conduct contract manufacturing processes, the need to ensure compliance with this standard is also to be considered. CTPA member companies have reported that administrative verification and/or inspections can still take up a significant amount of time (50-300 hours annually). Additionally, many companies may require support in understanding how these standards apply to their own facilities or seek to obtain a certification on these standards through third-party service providers. Obtaining and maintaining this certification ensures a simpler route to demonstrating compliance with an associated cost.

Should reliance on standards be extended to other areas, it is likely that product safety would thereby be met through a series of costly certification systems. This process being similar to conformity assessments, which ensure compliance but do not necessarily always ensure safety.

Furthermore, the absence of international or national standards could lead to the appearance of a number of commercial certification systems emerging with varying approaches to meeting the intended objective of the legislation. This would create uncertainty over which approaches would be legally acceptable, resulting in greater uncertainty. For example, if labelling requirements were only guidance, industry may be able to rely on the ISO 28219:2017 standards, but consumer organisations may require different information and individual companies may end up selecting neither and building their own approach. This would remove consistency and create a lot of unnecessary confusion to consumers who rely on this information to determine whether a product is suitable for them. A further example could be drawn from cosmetic ingredients, where the proliferation of certifications claiming to have authority over product safety may lead to the denigration of safe ingredients through unscientific reasoning, bringing into question the safety of products by consumers and international partners.

The impact of relying on guidance and standards in the context of enforcement actions also merits consideration. Absence of clear legislation would make it harder for enforcement to determine where a safety issue or non-compliance may be present and would likely require dialogue on scientific or toxicological principles. This would place additional burden on OPSS and Trading Standards, as well as the affected companies.

On cosmetic product safety

Clear legal rules guaranteeing product safety are key to ensure the protection and trust from consumers in the safety and efficacy of cosmetic products, to protect the reputation of the cosmetics industry and to promote OPSS as an effective regulator.

Research conducted by OPSS (Office for Product Safety and Standards, April 2021, OPSS Product Safety and Consumers: Wave 1) highlighted that one of the key indicators that consumers sought as reassurance of safety in cosmetic products was the trust on brand names. The cosmetics industry maintains a close relationship with consumers, one that is built on trust and the provision of products that are considered as essential by the majority of UK consumers.

This trust has been built on the basis of the UKCR, which dictates that only products which are safe for human health shall be made available to consumers. All cosmetic products must undergo a safety assessment before being placed on the market in order to demonstrate compliance with this principle. This assessment has to be completed by a safety assessor, qualified according to Article 10 of the UKCR, with sufficient toxicological knowledge to determine the safety of the use of the ingredients, in the given combination, in the context of the expected use and consumer target. Under the proposed approach, the expertise required may be significantly different, requiring companies to be able to identify hazard properties rather than evaluate the safety profile of the consumer product.

The cosmetics industry has continuously communicated with consumers, directly or through conventional and social media, key aspects of the UKCR as they relate to safety⁷. This safety system and consequent consumer trust may be jeopardised in a horizontal framework, unable to provide clear safety criteria for cosmetic products.

Safety assessments can be considered as a particular type of risk assessment in as much as it requires cosmetic products must be safe for the end user within the context of multiple factors such as the intended consumer, toxicological profile of each ingredient, packaging, microbiological quality, method for use, etc. This assessment dictated by the requirements of Annex I of the UKCR helps provide an overall understanding of the product and allows industry to work towards a common safety baseline. This is further supported by expert tools such as the SCCS Notes of Guidance, and the SCCS and SAG-CS opinions. However, this assessment is done in the context of the risk management measures already in place through the UKCR, such as the restriction of ingredients and the information provided to consumers. Replacing the safety assessment with a hazard-based approach may make it harder to determine what is meant by a 'safe product', allowing unsafe products to reach consumers, or limiting consumer choice.

Furthermore, the UKCR does not only regulate for safety, but includes a wider range of consumer protection measures which allow companies to promote, advertise and communicate the benefits and effectiveness of cosmetic and personal care products. These communications are also regulated not only through the general framework for consumer protection, but specifically within the UKCR.

As mentioned, the UKCR represents the current global gold standard for cosmetic safety. Any framework proposing to replace this regulation should be shown to provide equivalent or superior safety for the consumer of cosmetic products.

On the use of digital labelling

The cosmetics industry is interested in the possible advantages of digital labelling as a way to enhance the use of technology, meet the increasing demand for consumer information, and enhance consumer safety by communicating more closely with consumers.

CTPA would like to express support to the development of initiatives relating to the provision of information to consumers and authorities through digital means. The cosmetics industry is aware of the possible advantages of ensuring that the UKCR is able to keep up with the latest advancements in technology, including the ever-present access to information through smart devices.

Cosmetic products have definitive labelling requirements to ensure that consumers can purchase products with confidence, such as the ingredients list, claims and instructions for safe use and suitable warnings. Some labelling information may also be used by authorities to ensure an adequate market control such as the name and address of the Responsible Person and the batch code. This information is currently mandatory on the product label and packaging.

However, the cosmetics industry is concerned with the increasing amount of information which needs to be present on the product packaging, such as those requirements regarding the disposal and recyclability of packaging linked with environmental legislation. At a time where cosmetic products are trying to reduce the amount of waste through initiatives like smaller product packaging and labels, the pressure to provide more information on pack contrasts significantly. This is particularly relevant to the cosmetics industry where small products with limited packaging are frequent, such as mascaras, eyeliners or deodorants.

⁷ 'Are cosmetics safe?', thefactsabout.com (<https://www.thefactsabout.co.uk/safety-of-cosmetics>)

The cosmetics industry will follow with interest the consultation proposal and would like to invite an open future dialogue with OPSS to consider future applications to other sectors such as the cosmetics and personal care industry. The potential of this proposal is independent from the common horizontal framework proposal, as there is room within the UKCR to explore how consumers may access information online.

Online Supply Chains

The cosmetics industry is in favour of initiatives that will ensure a better degree of consumer protection against unsafe products. The growth of e-commerce and access to purchase options may not always provide consumers with products that meet the safety standards established in the UK. Transparency and clear roles and responsibilities remain one way of achieving greater visibility and promoting market surveillance.

CTPA is unaware of the scale of the challenge presented for the cosmetics industry with regards to the use of marketplace platforms, although concern does arise on occasion around the availability of counterfeit or second-hand products which could constitute a danger to consumers.

CTPA would also support the availability of relevant information to consumers when making online purchases. The UKCR contains strict requirements for the labelling of cosmetic products, and CTPA would welcome the opportunity to collaborate with OPSS in providing clarity for the cosmetics industry on how these requirements should be interpreted in the context of online retail.

Compliance and enforcement

CTPA welcomes initiatives which aim to support or enhance the effectiveness of the role of OPSS in broad terms. The reputation of the UK's cosmetics industry is not independent from the trust in OPSS from consumers and international regulators. CTPA is grateful for the continued interest of OPSS in participating to global forums such as the International Cooperation on Cosmetics Regulation (ICCR) which promotes ongoing dialogue on regulation for cosmetic products.

CTPA would like to offer some considerations as this approach is taken forward.

On the role of Trading Standards

During the call for evidence, CTPA was one of the respondents that supported an increase in cooperation with local authorities, Trading Standards, who continue to ensure consumer safety. Therefore, while considering how to enhance the leadership role of OPSS with local authorities, it must also be considered how this will in turn enhance the role of Trading Standards and enable them to ensure that legislation is enforced, to promote compliance with legal requirements and ensure consumer protection is guaranteed. We have noted and welcomed the creation of a team dedicated to act as a single contact point, but in promoting a greater leadership role this must also consider local authorities.

It must also be clear what the role of Primary Authorities (direct or partnership) will play. CTPA maintains a Coordinated Primary Authority Partnership that allows the exploration of compliance and best practices with Trading Standards on behalf of the industry. This has provided industry with key clarity in some areas, and we continue to explore how best practice can enable better market surveillance and promote compliance. Therefore, any increased responsibility in this area from OPSS should not conflict with existing arrangements.

Creation of a new legal gateway

Coordination and cooperation are not only key between OPSS and Trading Standards, but also across different UK Government departments. Data-driven decisions form the basis of many business decisions, and it follows that the same approach may be taken within the UK Government. As a part of the Department for

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Business and Trade, we understand the value of being able to share information that may enhance our approach to international relationships or provide a better understanding of the domestic context. Equally, the established regulatory and operational links with other frameworks regulating chemicals make it important that OPSS is able to effectively cooperate with other Government departments.

The extent in which this information is shared should be outcome-driven, and limited to only the information which is strictly necessary. Information should not be shared outside of the UK Government structure without prior consent, and no confidential or commercially sensitive information should be shared in this way.

A further proposal regarded the notification of recalls and serious product incidents directly to OPSS, bypassing local authorities, and the possible introduction of sanctions should these obligations not be met. The UKCR has clear provisions to support the in-market control of cosmetic products and the continued safe use of these products by consumers. One such provision is requirement for companies to record Undesirable Effects (UE) and report Serious Undesirable Effects (SUEs) to OPSS within a given period of time. It must be noted that these reports take into consideration a causality assessment where it must be determined that the SUEs were effectively caused by the particular cosmetic product, and the term SUE is clearly defined within the regulatory framework to allow companies to understand when their obligation to report is present. These provisions lay the foundation for the unique management of cosmetic SUEs which should be retained. Cosmetics cannot be grouped with other product types when it comes to assessing, managing, or reporting serious adverse effects.

In attempting to centralise this requirement it must also be considered that Trading Standards provide great business support through processes such as recalls and withdrawals. Therefore, effective communication with Trading Standards should be in place to ensure that businesses may be supported when trying to do the right thing and ensure consumer safety. This should also be taken into account when considering the introduction of penalties for failure to meet this obligation, and a pragmatic approach should be taken to ensure that no undue pressure is put on businesses where this was not to the benefit of consumer protection.

On harmonization of the enforcement regulations and sanctions

The cosmetics industry relies on the Cosmetic Products Enforcement Regulations 2013 to understand the consequences of failure to comply with the UKCR. This has been in place for some time, and industry is acquainted with the regulations to the extent that they understand when products may be deemed to be non-compliant, the allocation of liability and the sanctions, pecuniary or not, that are associated with the non-compliance. However, these regulations are not a common reference point or form part of general practice outside of explaining enforcement actions. Therefore, CTPA would like to express general support to an approach that may facilitate the role of Trading Standards and OPSS in enforcement. A harmonised, more transparent approach to enforcement regulations could provide the same level of information to businesses regarding the consequences of not following UK law, while ensuring that enforcement can be carried out in an effective manner. Industry would like to ensure enforcement powers and actions under OPSS are proportionate and do not go beyond what is currently in place for cosmetics.

It must be noted that the possible shift to a horizontal framework that relies on standards may make it harder to determine instances of companies that are outside of compliance and therefore in need of enforcement. It is likely to result in an increased burden during inspection and enforcement.

Should this approach be taken, CTPA would like to request consideration to guidance for industry on how to understand the consequences of breaking the law.

On the product liability regime

CTPA has noted the proposal to review the product liability regime for consumer goods, and that this is mainly to reflect the use of new technologies such as AI. However, CTPA members have expressed support for a product liability regime that would further support businesses.

Establishing a process which triages complaints at the point of submission, where claims without merit could easily be redressed/redirected would ensure that we are protecting the rights of consumers who have genuine issues and that are based on the quality or safety of a particular product.