European Commission

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	***Labelling fragrance allergens***
LEAD DG (RESPONSIBLE UNIT)	DG GROW (DG Internal Market, Industry, Entrepreneurship and SMEs) Unit D4 (Heath Technology and Cosmetics)
LIKELY TYPE OF INITIATIVE	*To be determined based on results of this impact assessment*
INDICATIVE PLANNING	*To be determined based on results of this impact assessment*
ADDITIONAL INFORMATION	*http://ec.europa.eu/growth/sectors/cosmetics/*

The Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

I. MEDICAL CONTEXT OF FRAGRANCE ALLERGIES. Contact allergy to fragrance allergens[1] may develop following skin contact with a sufficient amount of these substances. Contact allergy is an altered specific reactivity in the immune system, which entails recognition of the fragrance allergen in question by immune cells. It is *per se* a latent condition, i.e. without visible signs or symptoms, which persists lifelong. Upon each re-exposure to sufficient amounts of the allergen(s) eczema (allergic contact dermatitis) develops, which typically involves the face, the armpits and/or the hands. The disease can be severe and generalised, with a significant impairment of quality of life and potential consequences for fitness for work. Around 16% of eczema patients in the European population are sensitised to fragrance ingredients. It can be estimated that the frequency of contact allergy to fragrance ingredients in the general population in Europe is 1-3%[2].

The routine medical procedure to establish whether a person is sensitive to fragrance allergens is patch testing. Although the most commonly used patch testing procedure involves only baseline markers from two 'Mixes' (Mix I comprising 8 individual substances and one natural mix and Mix II comprising 6 substances), testing against more individual substances is practised by more specialised medical centres.

[1] Only contact (such as skin) fragrance allergens are in the scope of the present proposal. Respiratory allergens have a lesser importance for cosmetic products and the methodology of their qualification and quantification is not as well established as that for contact allergens.

[2] Source: SCCS Opinion of 26-27 June 2012 on fragrance allergens in cosmetic products (SCCS/1459/11), p. 7. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

II. RISK MANAGEMENT. The European Commission services approach to risk management of fragrance allergens in cosmetic products makes a distinction between primary and secondary prevention. While the former aims at protecting the whole population from acquiring allergies (through bans, concentration limits and other restrictions), the latter aims at protecting those who have already been sensitised from re-exposure to the substance which may result in manifestation of the disease. The provision of information about presence of an allergenic substance in the product is of particular importance for the sensitised consumer as they can be sensitised even to very low concentrations of allergens not covered by the primary preventive measures.

III. LEGAL CONTEXT. According to Regulation No. 1223/2009 ('Cosmetics Regulation')[3], the ingredients of the cosmetic product should be listed on its container and packaging in indelible, easily legible and visible lettering (Article 19 (1) in conjunction with 19 (1) (g) of the Cosmetics Regulation). Where it is impossible for practical reasons, the list of ingredients may also be included on 'an enclosed or attached leaflet, label, tape, tag or card' (Article 19 (2) of the Cosmetics Regulation).

According to Article 19 (1), 6th indent of the Cosmetics Regulation, "Perfume and aromatic compositions and their raw materials shall be referred to by the terms 'parfum' or 'aroma'". However, Article 19 (1), 6th indent further states that some of these substances shall be indicated in the list of ingredients in addition to the terms 'parfum' or 'aroma', i.e. they have to be individually labelled.

According to Annex III (column 'Other') of the Cosmetics Regulation, 26 fragrance ingredients have to be individually labelled, in addition to the terms 'parfum' or 'aroma'. Their presence has to be indicated in the list of ingredients if their concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products. These 26 substances were added to Annex III of the Cosmetics Directive[4] (replaced by the Cosmetics Regulation) by Directive 2003/15/EC[5]. This amendment was based on the final opinion adopted by the SCCNFP (Scientific Committee on Cosmetic Products and Non-Food Products) on 8 December 1999[6], which identified 26 fragrance allergens as an important cause of contact allergy reactions in fragrance sensitive consumers. Their labelling as a risk managements measure was introduced in order to ensure that such consumers are adequately informed, so that they can avoid cosmetic products containing a specific allergen.

In response to the Commission services' request for an update, the SCCS (Scientific Committee on Consumer Safety), which had replaced SCCNFP, gave Opinion of 26-27 June 2012 on fragrance allergens in cosmetic products (SCCS/1459/11), the '2012 Opinion'[7]. It stated that the consumer should be made aware of additional fragrance ingredients present in the cosmetic product, on top of those 26 already subject to individual labelling.

In the public consultation of 2014 the Commission proposed, among others, to Amend Annex III

[3] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342,22.12.2009, p. 59.

[4] Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. OJ L 262, 27.9.1976, p. 169–200.

[5] Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, OJ L 66, 11.3.2003, p. 26–35.

[6] http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf

[7] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

to the Cosmetics Regulation ('List of substances which cosmetic products must not contain except subject to the restrictions laid down') by submitting additional 62 contact allergens to the obligation of individual labelling, in addition to the 26 allergens already listed in Annex III. The allergens concerned, some of them derivatives of the same substance, would be those with the strongest scientific evidence, i.e. contact allergens established in humans as well as pre-haptens/pro-haptens which may be activated into them. For each of them, a requirement would be included in the column 'Other' of Annex III to indicate the presence of the substance in the list of ingredients, in addition to the terms 'parfum' or 'aroma', when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.

The public consultation met with a strong reaction from the industry, which challenged the labelling on the package and suggested e-labelling (online) labelling instead.

Should the Commission introduce the obligation to label additional 62 fragrance ingredients the number of fragrance allergens to be labelled would increase to 87[8] substances.

IV. IMPACT ON OTHER POLICIES. The labelling of additional fragrance allergens will have an impact on products regulated by Regulation 648/2004 ('Detergents Regulation')[9]. According to Annex VI, point A of the Detergents Regulation, the allergenic fragrances that appear on the list of substances in Annex III of the Cosmetics Regulation, as a result of adaptation to technical progress, shall also be listed according to the Detergents Regulation, if added at concentrations exceeding 0,01% by weight.

It will also have an impact on cosmetic toys regulated by Directive 2009/48 ('Toy Safety Directive')[10], which provides that cosmetic toys shall comply with the compositional and labelling requirements from the Cosmetics Regulation (Annex II of the Toy Safety Directive 'Particular safety requirements', part III 'Chemical properties', point 10).

However, the impact on both products regulated by the Detergents Regulation and the Toy Safety Directive would be limited to the decision on the labelling of additional fragrance allergens, and would not concern the form of labelling. The form of fragrance allergens labelling from the Cosmetics Regulation would affect neither the Detergents Regulation nor the Toy Safety Directive as these legal acts have their own provisions on labelling.

The existing policy is not part of the REFIT agenda.

Problem the initiative aims to tackle

Three main problems have been identified:

I. LACK OF CONSUMER INFORMATION ABOUT ADDITIONAL FRAGRANCE ALLERGENS IN COSMETIC PRODUCTS. The 2012 Opinion recommending that the consumer should be informed about additional fragrance allergens still needs implementation, which potentially causes harm to human health for sensitised consumers and deprives all the consumers of their right to information in this regard.

II. ISSUES WITH LISTING FRAGRANCE ALLERGENS ON THE PACKAGE OF COSMETIC PRODUCTS. If additional 62 allergens are to be labelled, the ingredient lists might get much

[8] The number of substances to be labelled may change due to the possible grouping of some substances. One of the 26 allergens currently subject to labelling (3 and 4-(4-Hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde) have been excluded from these calculations as it was banned by Regulation 2017/1410 of 2 August 2017. Transition periods for the ban end on 23August 2019 (for placing the substance on the market) and 23 August 2021 (for making it available on the market).

[9] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, OJ L 104, 8.4.2004, p.1.

[10] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p. 1–37.

longer (depending on the number of allergens in the cosmetic product). If smaller fonts are used, this could make ingredients lists more difficult to read for the consumer. Under the Cosmetics Regulation, lists of ingredients may also be attached to the products in the form of leaflets, tags, etc. The listing of fragrance allergens on the package may also incur additional costs for the industry as well as environmental costs, as longer list may result in the need for bigger packages/ additional leaflets and the like.

III. ISSUES WITH E-LABELLING. E-labelling is meant as an alternative option to on-pack labelling since the decision as to whether to e-label would be on the manufacturer. If additional fragrance allergens can be e-labelled (listed online), the challenge would be to ensure that all consumers (also those without internet access) would have access to the lists of ingredients at the point of sale. Notwithstanding the method of giving access to information (through a QR code, a website address or barcode), the consideration regarding access to information to non-users of internet would be the same, below.

If the obligation to give access to this information was on the retailers, lists of ingredients could be for example printed or shown on a screen in shops. If this obligation was on manufacturers, lists of ingredients could be made available for example via free-of-charge calls (info line), return text messages with lists of ingredients, etc. Moreover, the e-labelling as a novel concept for cosmetics should be assessed for its feasibility and costs both for the industry and the authorities controlling the national markets.

STAKEHOLDER MAPPING

The main groups of stakeholders affected by subjecting additional fragrance allergens to labelling and by the method of this labelling are listed below.

Consumers. Lack of information about all fragrance allergens in cosmetic products affects in particular allergic consumers who are not be able to avoid substances to which they are sensitised, but also affects the consumer right to information in general.

If allergens are listed on the package, the consumers would be affected by long lists of ingredients on the package as they will be less readable.

If allergens are e-labelled, consumers who do not have internet access at the point of sale (shop) could be deprived of information about allergens in the cosmetic product.

Cosmetics industry. Labelling additional fragrance allergens as such could increase reputation of the cosmetic industry for transparency and safety of ingredients. Irrespective of the form of labelling, the industry will incur costs of devising analytical methods of identification and qualification of additional fragrance allergens. The assessment of the impact on manufactures of cosmetic products should be complemented by the impact on manufactures of fragrance ingredients (such as essential oils), as they also may responsible for the identification and qualification of allergenic substances.

The industry largely supports the idea of e-labelling and is against labelling on the package, as the results of the public consultation of 2014 have shown. The labelling of additional fragrance allergens on the package would incur costs related to devising and producing new packages, withdrawing incompliant packages from the market and replacing them with compliant ones. Moreover, those costs would have to be incurred each time new allergens are included in Annex III for their labelling following new SCCS opinions. Longer lists of ingredients would also lead to damaging the artwork of the package and thus diminishing the visual attire of the product. Different options in which the manufacturer would facilitate access to the lists of ingredients to non-users of internet (free-of-charge info lines, etc.), their costs and feasibility, have to be further examined.

Retailers may be affected only in the case of e-labelling if there are additional obligations for them relating to giving access to the list of ingredients to consumers not having internet access. These obligations may involve giving access to either a paper or an online list of ingredients. While this option is to be examined further, it should not incur excessive additional costs or other burdens for retailers.

National authorities as exercising surveillance tasks would be affected by labelling as such and by

either form of labelling. It is in particular to be examined to which extent the labelling form matters for the authorities.

Dermatologists/specialists in allergies may find that labelling additional fragrance allergens facilitates allergy diagnosis and may prefer a specific form of labelling.

Basis for EU intervention (legal basis and subsidiarity check)

I. LEGAL BASIS OF POSSIBLE CHANGES: The general legal basis for action in the field of cosmetics labelling is Article 114 (1) of the Treaty on the Functioning of the European Union (TFEU), which provides that for the achievement of the objectives set out in Article 26 TFEU (establishing or ensuring the functioning of the internal market), the European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States. The procedural legal basis depends on the action to be taken, which can only be decided after the impact assessment is concluded.

If the regulatory action takes form of inclusion of additional allergens in Annex III of the Cosmetics Regulation with the obligation of indicating them on the package, the legal basis would be then Article 31 (2) of the Cosmetics Regulation. This Article provides for a regulatory procedure with scrutiny (PRAC) in case adaptations of Annexes III to VI and VIII to technical and scientific progress. The legal basis may be affected in the future by the result of discussions on the Alignment proposal[11], according to which PRAC should be replaced by either implementing or delegated acts, to adapt the existent legal procedures to Articles 290 and 291 TFEU (delegated and implementing acts).

If the chosen option is e-labelling, changes in the text of Article 19 of the Cosmetics Regulation may be required as Article 19 (1) refers to the obligation of labelling only on the 'container or packaging of the cosmetic product' (Article 19(1)). Such a change can only be done through an ordinary legislative procedure (Article 114(1) of the Treaty on the Functioning of the European Union.)

II. SUBSIDIARITY: The problem of labelling of fragrance allergens and the choice of its form should be solved at EU level for the following reasons: 1) The rules relating to the labelling of ingredients of the cosmetic product are already included in the Cosmetics Regulation and thus all Member States are obliged to apply them (harmonised rules); 2) Having common rules for fragrance allergens labelling is of utmost importance for the free circulation of cosmetic products in the internal market, therefore regulation at EU level is necessary and provides a benefit.

B. Objectives and Policy options

The main policy objective of the initiative on labelling of additional fragrance allergens is to inform the consumer about the presence of additional fragrance allergens in cosmetic products while ensuring that the information is easy to find and to read. The chosen option should not incur excessive costs for the industry and for the environment.

At least the following policy options will be analysed:

- **Option 1 'baseline': No EU action.**

The baseline scenario would imply no labelling of additional fragrance allergens. Although 1-3% of the European population is affected by contact allergy to fragrance ingredients, such an allergy is not life-threatening (it manifests itself as a skin condition). The considerations to be taken into account for this option are the following:

[11] Proposal for a regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (COM(2016)0799 – C8-0524/2016 – 2016/0400(COD).

Medical tests (patch tests) are not available for all fragrance allergens recommended for labelling by the SCCS in its 2012 opinion. However, labelling additional fragrance allergens may create an incentive (medical usefulness) to develop tests against additional substances.

Some improvement of the situation could be seen already now thanks to the commitment of the industry to increased consumer information. Some industry members are working towards increased transparency of ingredients of their products, this including online labelling. It is possible that in the future an increasing number of companies would follow this route, given the increasing importance of transparency to the consumer and the general development of online information. However, the labelling of fragrance allergens (for health safe reasons) cannot be left to voluntary action of the industry.

A legal argument for labelling fragrance allergens would be that according to Recital 9 of the Cosmetics Regulation, cosmetic products should be safe and risk-benefit reasoning should not justify a risk to human health. The SCCS indicated that some health risks might be attributed to use of fragrance allergens if used by allergic patients. Therefore, labelling fragrance allergens would increase safety of cosmetic products.

There are also numerous socio-economic arguments in favour of labelling fragrance allergens. Skin diseases in general are known to affect quality of life significantly. Skin conditions may affect self-image, limit social activities and lead to occupational restrictions (as a hairdresser, cosmetologist, etc.). Fragrance allergy may also lead to a sick leave. Fragrance allergy is the second most frequent cause of contact allergy after nickel allergy and is seen in every 10th patient investigated for contact allergy.[12]

- **Option 2. Labelling additional fragrance allergens according to the present rules of the Cosmetics Regulation, i.e. on the package of a cosmetic product or in other alternative ways (leaflets, tags, etc.) - 'on-pack' labelling**.[13]

This option would mean that approximately 87 fragrance allergens would be indicated on the package of the cosmetic product (or on an attached leaflet or the like).

A clear advantage of this option is that the consumer would have access to the list of all ingredients at the point of sale (shops), without the use of any additional device and without internet connectivity.

Moreover, this option can be introduced by a simple change to Annex III (i.e. inclusion of additional fragrance allergens to this Annex with the obligation of their labelling), done by the committee procedure under Article 31 of the Cosmetics Regulation, which is a relatively fast procedure. No legislative change of Article 19 of the Cosmetics Regulation would be needed.

E-labelling (option 3): E-labelling options have been suggested by the industry in the course of the public consultation of 2014. There are three labelling sub-options, depending on how the consumer would access the off-pack list of allergens: through a website address (sub-option 3 (a)), through scanning a QR code (sub-option 3(b)) or through scanning a barcode (sub-option 3 (c)).

In all of them, the manufacturer would make a final decision whether to opt for 'on-pack' (see option 2) or e-labelling (option 3) and in the latter cases would be responsible for managing the database with lists of ingredients. This would allow the manufacturer to make an optimal commercial choice and would also allow consumers to choose products which would be on-pack or off-pack labelled depending on their preferences. The e-labelling would give the possibility of checking the list of ingredients at the point of sale through the use of private devices, such as smartphones. Consumers could use their mobile internet (such as 3G/4G) access or already available Wi-Fi in the shops. Some retailers may also install devices (scanning equipment) allowing for the access to the list of ingredients at the point of sale for

[12] Source: SCCS Opinion of 26-27 June 2012 on fragrance allergens in cosmetic products (SCCS/1459/11), p. 29. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

[13] For the purpose of this Inception Impact Assessment, we will follow the terminology used by the industry in the public consultation in which the present labelling rules are called in short 'on-pack labelling', even though they allow also for labelling through tags, leaflets, etc. attached to the cosmetic product.

consumers without internet access or may have lists of ingredients in a paper version. The option of giving access to the ingredient lists through free-of-charge calls, return text messages with lists of ingredients, etc., as an obligation of manufacturers could also be envisaged. In such a case the obligations of giving access to the information would be on the retailer. The modalities of such an option are to be discussed in the course of this impact assessment.

E-labelling may cover either labelling of all fragrance allergens (including those already subject to labelling) or only 62 additional fragrance allergens.

Option 3 have three sub-options:

- **Sub-option 3 (a)**: e-**labelling fragrance allergens by means of a website address.**

This option requires displaying on the package of each cosmetic product a website address through which the consumer could access the list of ingredients.

- **Sub-option 3(b): e-labelling fragrance allergens by means of QR codes.**

This option requires printing on the package a QR code which upon scanning would give access to the list of fragrance allergens present in the cosmetic product. This option requires having a QR reading application on the device.

- **Sub-option 3(c):** e-labelling **by means of barcodes provided on the package.**

This option requires a barcode on the package which upon scanning would give access to the list of ingredients. This option requires having a barcode reading application on the device.

Sub-options 3 (a), (b) and (c) could easily be combined to give the widest access to the consumer information possible.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

Option 1 (No EU action) :

Positive/negative:

No direct costs for the industry, but no action could decrease the reputation of cosmetic industry for transparency and safety of ingredients.

There could be a shift of preferences of some consumers, especially those sensitised, to products which show more information on the content of cosmetic products because of voluntary action of the manufacturer. This may also trigger decrease of reputation of those products that show less information on allergens. This cannot however be assessed as a positive or negative cost for the affected industries (as these changes are within the affected product group, i.e. cosmetic products).

Option 2 ('on-pack' labelling):

Positive:

Better and easy to access information could induce consumers at risk of allergies to increase their demand for different kinds of cosmetics. Moreover, accurate labelling would strengthen the reputation of safety of European cosmetic products.

Negative:

- Costs of developing analytical methods to measure concentration of additional fragrance allergens in cosmetic products (as in the case of the 26 fragrance allergens already subject to labelling, the labelling obligation arises only above certain concentrations, different for leave-on and rinse-off products);
- Costs of re-designing of packages to include additional fragrance allergens;
- Costs of withdrawing non-compliant packages from the market;
- Cost of redesigning packages for export for manufacturers/importers who prefer to shorten their list of ingredients for exported products.

Option 3 (e-labelling):

Positive:

- Better and easy to access information could induce consumers at risk of allergies to increase their demand for different kinds of cosmetics;

- Possible future requirements to label new fragrance allergens would not require repeated withdrawals and re-designs as the list of allergens would be amended online.

N*egative:*

- Costs of developing analytical methods to measure presence and concentration of additional fragrance allergens in cosmetic products (in the case of the 26 fragrance allergens already subject to labelling, the labelling obligation arose only above certain concentrations for leave-on and rinse-off products);

- Some re-designing needed, which would consist of adding a website address or a QR code/an extended barcode;

- Need to develop and maintain/update internet websites with lists of fragrance allergens and train staff;

- One-off cost of withdrawing non-conforming packages from the market;

- Possible costs of giving access to full lists of ingredients to consumers not having internet access.

All the impacts mentioned might be particularly relevant for SMEs, for which some costs might be relatively higher. However, all companies, including SMEs, will have a choice whether to opt for on-pack or e-labelling, depending on their commercial choice.

Likely social impacts

Option 1:

Negative:

- Lack of information about additional fragrance allergens in the cosmetic product would make it impossible for allergic consumers to check whether a cosmetic product contains harmful substances.

This may result in human health risks as these consumers may have an allergic outbreak after the use of such products. Lack of labelling of fragrance allergens would also affect the general right to the consumer information.

Option 2:

Positive:

- Information on all ingredients easily accessible at the point of sale.

Negative:

- Decreased readability of a list of ingredients due to the large number of ingredients listed and possibly smaller fonts used.

Option 3:

Positive:

- Better readability of a list of ingredients compared to option 2; possibility to enlarge the font on the screen of a device (important for people with vision impairments);

- Faster adaptation to future regulatory changes requiring the labelling of new fragrance allergens (only time needed to develop analytical methods for qualifying and quantifying new substances would be taken into account while calculating transitional periods; no need for additional time to withdraw products from the market and to redesign packages);

- Opens the door for optional facilitations, which could include the possibility of checking a list of online ingredients from home or using a 'search' function for a specific substance; these could also be useful for doctors in the diagnostic of allergies.

Negative:

- No possibility of checking all fragrance allergens contained in the product at the point of sale without

personal devices with internet access, unless the retailer/ manufacturer provides such a possibility.

Likely environmental impacts

Option 1:

No impact.

Option 2:

Negative impact:

- An increase in the volume of packages/need for additional packages/leaflets, etc. and withdrawal of non-compliant packages from the market would cause environmental waste.

Option 3:

Negative impact:
- A one-off need for withdrawal of non-complying packages.

Likely impacts on fundamental rights

No expected impact

Likely impacts on simplification and/or administrative burden

Options 2-and 3: New labelling obligations will be subject to surveillance of authorities of Member States, as any other regulatory compliance obligation under the Cosmetics Regulation. For that reason, the Member States will have to develop analytical methods for measuring the content of fragrance allergens in the cosmetic product.

Other investments may include additional training for staff responsible for cosmetics surveillance.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment is being prepared to support the preparation of this initiative. The impact will compare different options labelling, i.e. labelling on the package and e-labelling (through the use of a website address, a QR code or a barcode) in terms of costs and feasibility for the industry and their feasibility for the consumer.

Evidence base and data collection

The following information gaps have been identified so far to verify feasibility of different forms of labelling:

1. The number of products to be affected by the labelling of additional fragrance allergens;
2. The increase in the size of a package when additional allergens are listed;
3. Costs of developing analytical methods for identification and quantification of additional fragrance allergens in the cosmetic products under the assumption of various transitional periods;
4. Costs relating to re-designing of a package with the aim of: 1) adding new ingredients to the list of ingredients on the package, 2) adding a website address/QR code/barcode to the package under the assumption of various transitional periods;
5. Costs of withdrawing non-compliant packages from the market under the assumption of various transitional periods;
6. Cost of creating and maintaining/updating a database with lists of ingredients of cosmetic products for the purpose of labelling;
7. Socio-economic costs of fragrance allergens labelling (cost of cosmetic-related allergy treatment, sick leaves, etc.)
8. Possession of smartphones in the EU (by country, by age and overall) and QR and barcode reading applications on these smartphones;
9. Availability of free-of-charge QR and barcode reading applications;
10. Internet coverage in Europe (Wi-Fi and mobile internet) in shops;
11. Environmental costs of on-pack labelling of additional fragrance allergens, including costs of

withdrawing packages of cosmetic products from the market under the assumption of various transitional periods and costs of bigger packages;

12. Consumer preference for on-pack and e-labelling (its different options), with special consideration for consumers who do not have the possibility of internet access in shops (who do not have smartphones); by country, age and overall;
13. Possibilities to provide lists of ingredients to consumers without internet access by retailers or manufacturers (paper lists of ingredients for each product, screens with lists of ingredients provided in shops, free-of-charge calls, other); opinions of all stakeholders about such options (consumers, manufacturers, retailers, national authorities).
14. Information on how many industry members would choose on-pack and how many e-labelling if given the option.
15. Impact of different labelling options on export of cosmetics.

Consultation of citizens and stakeholders

The following groups of stakeholders will be consulted on the costs and benefits of the different policy options: consumers (including allergic consumers and consumers without internet access), consumer organisation(s), industry representatives and members, including manufactures of ingredients for fragrances, representatives of retailers/ retailers, the national authorities and dermatologists. All industry consultations will pay special attention to SMEs. Views of cosmetic toy industry and detergents industry will also be taken into account to the relevant extent.

The expected timing is the following:

- Public consultation (minimum period of 12 weeks). Indicative starting time: May 2019;
- Targeted consultations through targeted questionnaires, in-depth interviews with relevant stakeholders and one or two events organised within the EC premises. Indicative starting time: April 2019.

The launch of the public consultation related to this initiative will be announced through the following website: https://ec.europa.eu/info/consultations_en

The synopsis report (a summary of all consultation activities' results) will be published on the consultation page once all consultation activities are closed.

Will an Implementation plan be established?

Depending on the outcome of the impact assessment, different legislative actions would be considered. In any case, for the moment, there is no need for implementation plan envisaged.