EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Cosmetics and Medical Devices

SYNTHESIS DOCUMENT – OUTCOME OF PUBLIC CONSULTATION ON THE DRAFT COMMISSION RECOMMENDATION ON THE EFFICACY OF SUNSCREEN PRODUCTS AND CLAIMS RELATED THERETO

1. INTRODUCTION

Sunscreen products are cosmetic products according to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[1] ("**Cosmetics Directive**"). They have an important "protective" function against UV radiation.

Therefore, the efficacy of sunscreen products, and the basis on which this efficacy is being claimed, are important public-health issues.

In particular, concerns have been voiced about the following aspects:

- Products should contain protection against all dangerous UV radiation;
- Products and claims should provide sufficient guidance to help consumers choose the appropriate product;
- Products should provide guidance on the correct application of the product.

In order to address these concerns, the Commission intends to issue a recommendation on various aspects of efficacy and claims relating to sunscreen products**.**

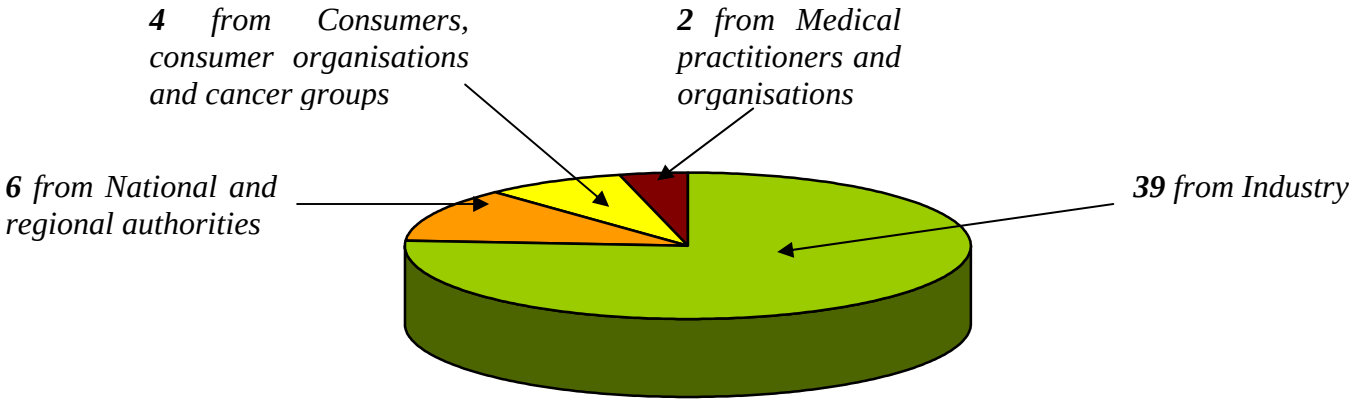
This recommendation will spell out

- claims which should not be made in relation to sunscreen products;
- precautions to be observed, including application instructions;
- the minimum efficacy standard for sunscreen products in order to ensure a high level of protection of public health;
- simple, understandable labelling to assist in choosing the appropriate product.

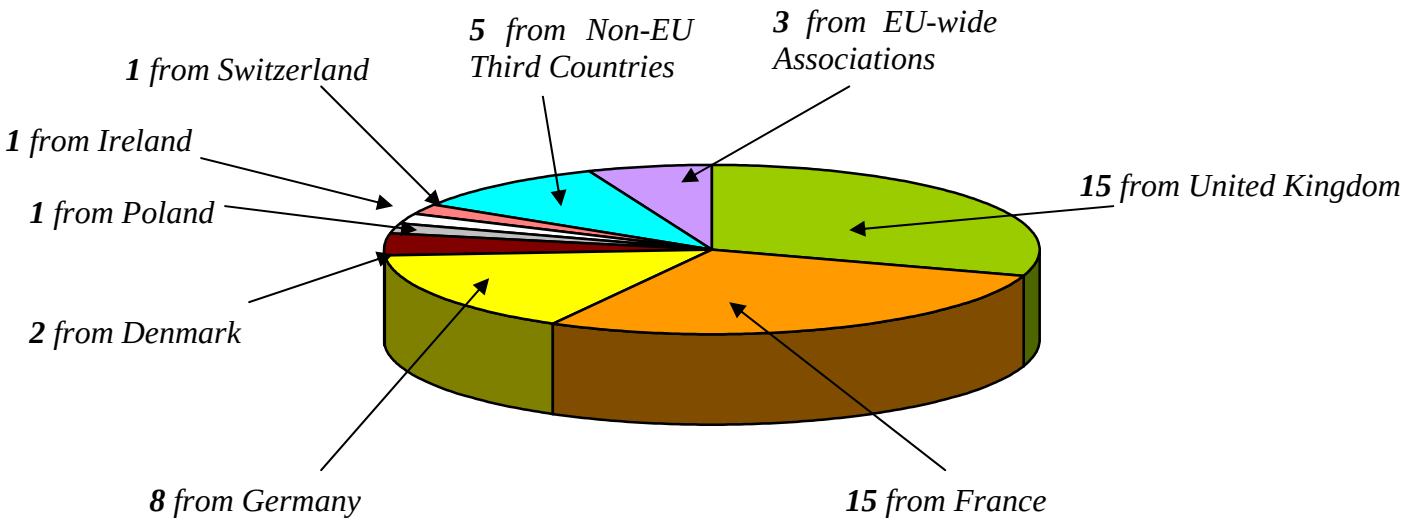
A draft recommendation has been drawn up by an expert group chaired by the Commission. On the basis of this draft, the Commission invited stakeholders to submit comments by 14 June 2006.

[1] OJ, L 262, 27.9.1976, p. 169, as amended.

In response to this public consultation, the Commission received 51 contributions. Of these, 39 originated from Industry (fine chemicals, cosmetics, others), six from national and regional authorities, four from consumers, consumer organisations and cancer groups, and two from Medical practitioners and their associations. The contributions from industry were in parts identical.



In terms of regions, three contributions originated from EU-wide associations, 15 from the UK, 15 from France, eight from Germany, two from Denmark, one each from Ireland, Poland and Switzerland, and five from non-European Third Countries.



As most contributors requested that their statements remain confidential, the Commission has decided to not publish the individual contributions for the time being.

2. GENERAL FEEDBACK

The initiative was **welcomed by the vast majority of submissions** as being an issue that needed to be addressed.

In particular consumer organisations, cancer groups and dermatologists were strongly supportive of the initiative. Some regretted the non-binding nature of the document.

Industry welcomed the initiative subject to various modifications of the draft text. The Commission will address some of the proposed modifications below (3.).

Most of the issues addressed in the various submissions had already been subject to intensive discussion in the working group on cosmetics products, composed of Member States and stakeholders, including industry and consumer associations. Within this group, the compromise outcome was the draft recommendation. Some contributions recognised that the challenge of balancing the needs of the different groups has been successfully met and acknowledged the careful and thoughtful drafting of the document.

Many contributions, mainly from industry, pointed out that there are **already ongoing initiatives in this field** and that much of what is recommended is already good practice. This should be more clearly acknowledged in the text. The Commission is going to consider this.

3. SPECIFIC COMMENTS

3.1. Scope

Several comments made the criticism that the scope of the draft recommendation was not clear concerning daily care and decorative cosmetics. One proposal was even to draw up a list of products which are covered by the draft recommendation.

The Commission considers that the definition of sunscreen products, which closely follows the definition of cosmetic products in the Cosmetics Directive, is clear. Its wording shows clearly that only products which are "exclusively or mainly" intended to protect from UV radiation are covered by the draft recommendation. This is usually not the case for daily care and decorative cosmetics.

Two comments requested the **inclusion of daily care products in the scope**, as far as UVA-protection is concerned. The Commission considers this inappropriate: the initiative should be limited to products which are intended to exclusively or mainly protect against UV radiation.

3.2. SPF labelling and categories

A large part of the submissions addressed the issue of sun protection factor ("**SPF**") labelling and the categories.

Some submissions pointed to the exponential increase in the SPF which might justify a "cap" on the labelled SPF at 30, or even completely abolishing the labelled SPF. One comment pointed out that any differentiation above SPF 30 does not make sense, as a significant difference in protection can only be attained if dosage and application are extremely accurate, which is not the case for practical application by the consumer.

On the other hand, many submissions pointed out that, while few consumers understand the exact meaning of the SPF, they are familiar with the number, which is based on largely identical testing methods in the EU and abroad.

Submissions from industry also supported a **restriction on the labelled SPFs**, but requested the possibility of using additional SPFs, such as 2, 4, 8, and 40. The importance of the market for SPF 2 was highlighted.

The Commission would like to underline that one objective of the draft recommendation is to make products more comparable for the consumer, and that minor step-wise increases in the SPF are not of major significance for a high level of consumer protection.

Moreover, as regards SPF 2 and 4, the Commission disagrees that these products can count as "products intended to exclusively or mainly protect against UV radiation". A number of studies have confirmed that consumers do not apply the quantities needed to achieve the level of protection claimed. This was also confirmed in a number of comments. Therefore, products with this degree of protection should not claim to "protect from" or "screen" sun radiation.

The fact that some MS have a market for "sunscreen" products of SPF 2 does not weaken this argument. It rather confirms the need for action.

This does not mean that cosmetic products cannot contain a UV filter of SPF 2 or 4. However, such products should not be presented as "exclusively or mainly protecting against UV radiation".

Concerning the **descriptive categories**, there was widespread agreement that a descriptor is a useful communication tool. It was pointed out that these descriptors can be kept while the conditions for each descriptor may be changed in the light of new scientific findings in the future. Disagreements concerned details: some submissions considered three categories to be sufficient. Several contributions requested an "ultra" category.

However, in various discussions with stakeholders and Member States it was agreed that terms like "ultra" should not be used to describe the efficacy of a sunscreen product, whose potency to address the various risks stemming from UV radiation has not been fully explored.

Two comments proposed that a sunscreen product of **SPF 15 should be categorised as "high protection"**.

However, in discussions with Member States and stakeholders it was agreed to take the normal conditions of use into consideration when attributing the categories. Several studies show that the quantity of sunscreen product used by the consumer is up to four times lower than under testing standards. Therefore, the Commission does not intend to change the distribution of SPF within the categories.

As concerns the **two options** which were submitted for public consultation, the vast majority of contributions considered option 1 to be preferable. Some

submissions pointed out that option 2 confuses the level of protection with issues of exposure and seems to restrict a product to particular uses only.

Within industry, there was unanimous criticism of the requirement to label the **"category" more prominently than the labelled SPF**. Several contributions proposed that the category be labelled "at least as prominently" as the labelled SPF. The Commission is going to consider this proposal.

3.3. UVA labelling

The initiative to recommend a **standardised label for UVA protection** was widely welcomed.

While some submissions considered that UVA protection should be obligatory anyway (and hence no labelling required) others were in favour of indicating the level of UVA protection in degrees. One submission proposed allowing a labelled SPF only if a certain UVA-protection level had been attained.

The question whether UVA protection should be indicated at all had been discussed at length with Member States and stakeholders in the run-up to the draft recommendation. It was agreed that, as UVA protection is still not a legal obligation, an appropriate label was necessary.

This, in turn, raised the question how the UVA protection should be indicated. The draft recommendation calls for claims – in particular for UVA protection – which are "simpler, unambiguous and more meaningful". It is industry's responsibility to develop such claims, and industry is urged to liaise with consumer associations to this end.

In any case, in the Commission's view there is little chance of achieving simpler and more understandable labelling by combining different degrees of protection for different wavelengths (i.e. UVB and UVA). The Commission considers it more appropriate to ensure that the **UVA protection increases with a rising SPF**, i.e. the higher the SPF, the higher the UVA protection. This would provide a simple indication of UVA protection while ensuring a rising UVA protection with an increasing SPF.[2]

Many contributions from UK-based industry highlighted the fact that there is **already now a UVA label** in the UK market, and that this should be considered by the Commission.

The Commission is aware that the UK market already has a UVA label, which, due to market characteristics, is perceived as "standard". The recommendation **in no way** "prohibits" this label. It merely recommends that manufacturers claim UVA protection in a "simple, unambiguous and meaningful manner". While the Commission considers that it is in the interest of industry to develop a Community-wide standardised level of protection

[2] This raised the question of the ratio of UVB and UVA protection and how the latter should be measured (on these two points, see below, 3.4.).

against UVA radiation, every manufacturer is free to apply such a standardised label. **On the other hand, no manufacturer can expect the Commission to recommend "Community-wide" a specific, existing label which is already in use by a specific manufacturer and thereby give that manufacturer a competitive advantage.**

3.4. Testing methods

3.4.1. General remarks

The bulk of comments were concerned with testing methods and with the criteria for labelling UVA protection. The contributions showed that, while there is widespread agreement on how to test for protection against erythema-inducing radiation, the question of how to measure other wavelengths is still subject to debate.

On the other hand, many contributions recognised the need to address this issue today on the basis of available knowledge: "Taking a decision on a UVA assessment now does not mean that there is no room for further improvement".

Some contributions pointed to ongoing initiatives to develop **entirely new approaches** to efficacy-testing of sunscreen products such as measuring DNA-damage on cultured skin cell models and measuring UV-induced free radicals in excised human skin.

The Commission has an interest in the swift "implementation" of this recommendation. This policy aim is difficult to reconcile with the development of an entirely new testing method. However, the Commission is going to follow closely developments in this field and urges industry to be open-minded with regard to new developments.

Some comments wondered whether it was really necessary to reproduce the testing methods in the annexes. The Commission is going to consider alternatives.

Several submissions pointed to the fact that all the tests set out are based on **unrealistic application scenarios,** linked not only to the quantity used, but also to the fact that sunscreen products are rubbed into the skin, which decreases their efficacy. One contribution doubted whether the quantity used in the testing methods can actually be taken up by the skin at all.

Another contribution highlighted the need to assess photostability not with regard to the product as a whole, but with regard to each individual filter.

The Commission is aware that the testing conditions are not fully realistic. In order to address this shortcoming, the draft recommendation provides for various measures, such as usage instructions and relatively high SPFs in the various labelled categories.

3.4.2. SPF testing method

One submission proposed adopting the US version of the SPF test. However, the Commission considers that this would give the wrong signal, as the "International Sun Protection Factor Method" has just recently been endorsed by the American Trade Association CTFA.

3.4.3. PPD testing method

There has been intensive discussion about the pros and cons of the various testing methods for other than *erythema*-inducing radiation. The core message of almost all submissions is threefold: first, any test should take photostability into account; second, the "perfect method" has still to be developed; and, third, the difficulty lies in finding a biological endpoint for long-term effects.

Several submissions asked for a clearer statement that the PPD test should only be recommended as a "reference-test" and that other, correlating tests are not excluded. In particular, these submissions criticised the definition of "UVA protection factor" as referring to just one specific method.

The Commission clearly **does not recommend restricting the number of potential testing methods for UVA radiation to a single one**. However, as the purpose of the recommendation is to recommend a minimum level of protection, there is a need to describe a standard to establish this minimum level, which, in turn, requires some basic definitions.

The Commission, as well as several Member States, industry and other stakeholders, had intensively studied the existing state of knowledge in assessing which test should be recommended as the "reference" for establishing a minimum level of protection from non-*erythema* inducing radiation. Moreover, a working group of the *Agence francaise de sécurité sanitaire des produits de santé* has assessed the scientific findings in this field, the outcome being submitted to an expert group within the working group "cosmetics products". The findings indicate that, while pigmentation is not a surrogate marker for UVA-induced damage as is *erythema* for UVB-induced damage, there is a relationship between certain biological damage to the skin and UVA-protection as assessed in the PPD method.

In the light of these findings, the Commission agreed with Member States and stakeholders, including the European cosmetics industry, to recommend the PPD-test as the reference for a minimum level of UVA protection.

The result of the consultation backs the Commission in this choice. Several submissions pointed out that the PPD method is the most widely-used test method. It takes photo-degradation into account and relates to a biological effect. Moreover, several contributions confirmed that – while pigmentation is an imperfect biological event

– there is a relationship between the biological effect of pigmentation and various immunological reactions in the skin.

Some submissions commented on the **shortcomings of the PPD method**. Reference was made *inter alia* to the need to expose volunteers to relatively high doses of UVA radiation, to the exclusion of several wavelengths due to the filters used in the PPD-test, to a possible flux-dependency and the effect of flux on the assessment of photo-stability, and to the difficulty of reproducibility.

With regard to the ethical considerations, the Commission re-emphasises the urgent need for finalising the *in-vitro* PPD method, which is a work in progress. On the issue of reproducibility, the difficulties are similar to those of the SPF test. With regard to the possible exclusion of certain wavelengths in the PPD test measurements, this argument supports the Commission in its main policy that no sunscreen product should claim total protection. As to other technical comments, the Commission takes them seriously and will raise them as part of the CEN standardisation procedure.

One submission asked why the **test differed slightly from the test as applied in Japan**. These slight changes had been proposed by the *Agence francaise de sécurité sanitaire des produits de santé* during discussions with Member States and Industry, including stakeholders, in order to adapt the test to the most common phototypes in Europe and in order to enhance reproducibility.

Finally, the question was raised as to who is in charge of **validation of the test method** as annexed to the draft recommendation. The Commission intends to endorse these tests through a submission to the European standardisation body, CEN. This is the appropriate body to undertake further work on the tests, as necessary, and to adopt a pan-European testing method.

3.4.4. 1/3 UVA-UVB protection ratio

The idea of fixing a ratio of UVA to UVB protection was welcomed during the public consultation: “This brings products closer to sun protection, rather than sunburn protection”.

Some contributions discussed the recommended ratio of 1/3 of the result of the PPD test in relation to the sun protection factor (hereinafter “**UVA/UVB ratio**”). While some contributions considered this ratio too ambitious, in particular for products with a high SPF, others thought the ratio should be ½, or 1/1.

The Commission, along with a number of Member States, industry and other stakeholders, had intensively studied the existing knowledge in assessing which ratio should be recommended for establishing a minimum level of protection from non *erythema*-inducing radiation. Moreover, a working group of the *Agence francaise de sécurité sanitaire des produits de santé* has assessed the scientific findings in this field and submitted its findings to an expert

group within the working group "cosmetics products". These scientific findings show that certain biological damage in the skin can be prevented and/or reduced if the ratio of the protection factor, as measured in the persistent pigment darkening test, is at least 1/3 of the factor measured under the sun protection factor testing method.

In the light of these findings, the Commission agreed with Member States and stakeholders, including the European cosmetics industry, to recommend a UVA/UVB ratio of 1/3. While this is an ambitious aim, it is nevertheless an attainable objective in the absence of a better surrogate marker.

Several contributions criticised this rather ambitious aim: it was pointed out that it is technically difficult to attain correlating (high) UVA protection in the range of high SPFs. One submission argued that a high UVA protection level can only be attained with chemical filters and that this creates a competitive disadvantage for manufacturers who rely exclusively on physical filters.

The Commission is aware that a high degree of UVA protection may make a combination of physical and chemical filters necessary. However, the Commission would point out that the dichotomy "physical filters – UVB", "chemical filters – UVA" is overly simplistic. This is shown by the trend towards physical filters, which is partly due to manufacturers' interest in covering a wider spectrum of UV radiation.

Several contributions asked whether the 1/3 ratio referred to the measured or to the lablled SPF. The Commission is going to consider this issue for clarification.

3.4.5. Critical wavelength test and other tests

Several contributions pointed to existing *in-vitro* tests, such as the critical wavelength test ("**CW test**") and the German Standard DIN 67502.

The CW test was characterised by some commentators as "simple, accurate and cheap", while others pointed out that the CW is not precise enough and is not linked to any biological action spectrum or biological event.

The Commission considers the CW test as a helpful additional criterion for assessing efficacy. The test is relatively easy to perform and helps to ensure that the protection is "spread" over a large part of the UV spectrum. Therefore, this test is recommended as an additional method.

As to the German Standard DIN 67502, several contributions pointed out that it was a promising starting point for developing an *in-vitro* PPD test. Some commentators made the point that this standard, while not taking photodegradation directly into account, nonetheless does so indirectly as it is linked to the SPF test.

3.5. Labelling of usage instructions and warnings

Several commentators requested clarification as to whether the wording of usage instructions and warnings can **differ from the sentences set out in the draft recommendation**. The Commission considers that this is clear from the draft text and in particular from the wording "such as". What counts is that the message is clearly and unambiguously conveyed.

There was widespread agreement that product labelling cannot replace tailored and understandable information through other channels, including the media and professionals. One commentator pointed in particular to the political responsibility of national governments to communicate health risks.

There were numerous requests to add **additional warnings** aimed, for example, at particular risk-groups, such as young children.

The Commission, in the draft recommendation, had to strike a compromise. In particular, it had to accept that product labels cannot be a substitute for providing the consumer with proper information by other means, and that information overload is to be avoided.

Several submissions commented on the two labelled phrases referring to **re-application**. Some contributions proposed giving more precise information on how often a product needs to be re-applied. Others drew the Commission's attention to products which are marketed with the claim "one application suffices". While some contributions considered these claims to be "very dangerous and grossly misleading", others argued that future innovations and developments might make a re-application unnecessary.

The Commission, when working on drafting these phrases with industry, consumer organisations and industry, had to reconcile three aspects: first, to put an end to the perception that a product can be used "under any circumstances" without re-application; second, to compensate for faulty application (too little, parts of body "left out", reduced protection through rubbing/sweating etc); and third, to avoid the impression that total time in the sun can be continuously extended through re-application.

With regard to the first point, no submission was able to substantiate that there are products on the market which give all-day protection "under any circumstances".

Moreover, despite some calls to do so, the Commission opposes giving a precise indication of the duration of protection, on the grounds that this would run counter to the policy aim of avoiding an extension of sun-exposure through re-application.

All submissions welcomed the proposal to make a **reference to the quantity to be applied** and commented merely on specific details in the draft recommendation. For example, the reference to measurement devices was criticised. Others criticised the fact that the quantity to be applied cannot be expressed in a general manner, which is mainly due to different body sizes.

The Commission would like to point out that such measurement devices (for example, pumpsprays) are not uncommon on the market. Moreover, the Commission realised that it is not easy to communicate the quantities to be used in an understandable manner. However, as the use of sufficient quantity has always been considered a crucial element in improving the way sunscreen products are applied, the Commission feels it must insist on this element.

Some contributions made an alternative proposal to label the need to apply the product in two initial applications. The Commission is going to consider this proposal.

In terms of a timeframe for application, some contributions asked for the labelling to call for an application 15 or 20 minutes before exposure, while others proposed referring to an application "just" before exposure. The Commission prefers to leave this issue to the manufacturer. However, it should be noted here that, in general, an application well before exposure is not required to ensure that a sunscreen product is effective.

3.6. Miscellaneous

3.6.1. "Implementation"

Submissions from industry welcomed the absence of an inflexible "implementation date". The difficulties involved in implementing the recommendation by summer 2007 were highlighted, stressing that the requisite timeframe was in fact between two and five years.

The Commission's policy is clear: **Industry is not legally required to take off the shelf products which do not comply with the recommendation.** However, politically speaking, the Commission expects industry to take steps so that the recommendation becomes "visible" for the consumer in summer 2007.

The Commission would reiterate that the choice of the legal form of a "recommendation" was in the interests of swift, but flexible implementation. Moreover, the Commission would like to point out that many recommended changes can be initiated already today without awaiting the final wording of the recommendation. Finally, the Commission has difficulties in understanding why a sector which claims to constantly innovate, re-brand and re-formulate (which justifies the absence of pre-marketing controls) can argue on the other hand that it would take up to half a decade to implement changes in the field of sunscreen products.

3.6.2. Safety of UV filters

Some submissions addressed the safety of UV-filters as such. These remarks referred to specific filters (such as 4-MBC) as well as to chemical filters in general.

The Commission would like to point out that UV-filtering substances – both physical and chemical filters – are regulated by the Cosmetics Directive. Every UV-filter used in cosmetic products has to undergo

a safety assessment by the Scientific Committee of Consumer Products ("**SCCP**") and needs to be authorised by the Commission. Concerning the concrete example of 4-MBC, the Commission as risk-manager has obliged industry to submit additional data to the SCCP to prove the safety of this substance. The evaluation is currently ongoing and the Commission is going to take the appropriate steps as soon as the risk-assessment in the light of this new data has been finalised.

3.6.3. Waterproofness

One submission proposed addressing the "waterproof" claim in the draft recommendation too. However, the Commission believes that the priority at the present stage is to address the most pressing issues, i.e. mainly UVA protection. The issue of "waterproofness" is in any case addressed indirectly through the labelled instructions. However, the Commission does intend to monitor the situation closely for possible follow-up action.

3.6.4. Additional consumer information

Several submissions came up with ideas for additional initiatives in this field: the need to provide for information at the "point of sale" was highlighted, as well as the need to launch additional initiatives well in advance.

3.6.5. Drafting

A number of suggestions were made to improve the drafting. In particular, some comments pointed out that it was overly simplistic to equate UVB radiation with the SPF.

The Commission is aware that the SPF addresses all *erythema*-inducing radiation. This is also reflected in the draft recommendation (e.g. *recital* No 10 and section 1 (2) (g)). However, some parts of the test required a simplified form of wording to make them more readable.

Other proposals for drafting changes will be duly considered by the Commission when finalising the text of the recommendation.

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