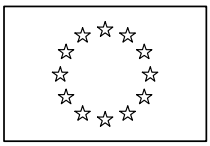

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COMMISSION STAFF WORKING PAPER

Impact assessment report on simplification of the "Cosmetics Directive" – Directive 76/768/EEC

Executive summary

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COMMISSION STAFF WORKING PAPER

Impact assessment report[1] on simplification of the "Cosmetics Directive" – Directive 76/768/EEC

Executive summary

Simplification of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[2] (the "**Cosmetics Directive**") was announced in the Commission Communication "Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment"[3] and in the Commission's Annual Policy Strategy for 2007.[4]

This simplification pursues **four objectives**:

- **Objective 1**: To remove legal unclarities and inconsistencies. These inconsistencies can be explained by the high number of amendments (55 to date) and the complete absence of any set of definitions. This objective also includes several measures to facilitate management of the Cosmetics Directive with regard to implementing measures;

- **Objective 2**: To remove divergences in national transposition which do not contribute to product safety but add to the regulatory burden and administrative costs;

- **Objective 3**: To ensure that cosmetic products placed on the EU market are safe in the light of innovation in this sector;

- Objective 4: To introduce a possibility in exceptional cases to regulate CMR 1, 2 substances on the basis of their actual risk.

It must be emphasised that **these objectives must not**:

- compromise the high level of product safety in this sector today;

- lead to changes to the arrangements for phasing out animal testing;

- have a negative impact on the functioning of the internal market for cosmetic products; and

- create unnecessary differences from the regulatory frameworks in non-EU states.

Analysis and comparison of the various options and their impact lead to the **following conclusions**:

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1 Based on the European Commission Impact Assessment Guidelines of 15 June 2005, including the March 2006 update. The format and structure of this report follow Annex 16 to the Guidelines.

2 OJ L 262, 27.9.1976, p. 169, as amended.

3 COM(2005) 535 of 25.10.2005.

4 COM(2006) 122 of 14.3.2006.

With regard to objective 1, the impact assessment supports **amendment of the Cosmetics Directive** as the only effective means of achieving this aim effectively thereby reducing regulatory burdens considerably. For example, the impact assessment shows potential to reduce administrative costs due to notification to anti-poison centres by approx. 80% compared with today. The clarification and streamlining of various provisions – including those on labelling – facilitates compliance without compromising product safety.

With regard to objective 2, the impact assessment supports a **recast into the form of a Regulation**. In particular, this is supported by the fact that the Cosmetics Directive is very detailed and frequently amended (approximately three to five times a year in recent years). Albeit minor, the differences in the 27 national transposing laws create additional costs for industry without contributing to product safety.

With regard to objective 3, the impact assessment supports striking a **better balance between "manufacturer responsibility" and "prescriptive regulation of individual ingredients"**: This is a crucial element, as the Cosmetics Directive is still shaped by the original concept – developed 30 years ago – of regulation of all substances used in cosmetic products "ingredient by ingredient". Today it is acknowledged that this approach alone is not sufficient to ensure that cosmetic products placed on the market are safe. Instead, the manufacturer responsibility and in-market control aspects need to be strengthened to make sure that products from this innovative sector will be safe in the future. This includes:

- clear minimum requirements for the cosmetics safety assessment which is being controlled via in-market surveillance;

- a system of administrative cooperation of competent authorities: this entails a system of coordination of Member States in the assessment of products and their supporting information, including rules for product withdrawal;

- a system of "cosmetovigilance": this entails an obligation of industry to actively report serious undesirable effects to competent authorities in order to early detect safety-risks caused by cosmetic products; and

- a notification requirement which provides for information to all competent authorities of the internal market through one single notification portal.

The most important element in term of impact is the introduction of clear minimum requirements for the cosmetics safety assessment. Up until now, there were no clear legal prerequisites for the contents of a cosmetics safety assessment. This has contributed to a relatively high degree of non-compliance. Clear minimum requirements increase the costs for companies which so far refrained from establishing a robust cosmetics safety assessment prior to placing the product on the market.

However, the impact assessment shows that there are a number of measures which soften the impact of this requirement. For example, a large part of these costs is outbalanced by the considerable decrease of administrative costs. If there is nevertheless an increase of costs compared to today, this can be justified on the strength of the benefits brought about by this option.

In terms of objective 4, the impact assessment supports the **possibility to allow under certain strict circumstances substances which are clearly safe but classified on the basis**

of hazard as CMR 1, 2 substances. Additional safeguards shall ensure that risk-based regulation of these substances would be the exception to the principal rule of a ban.