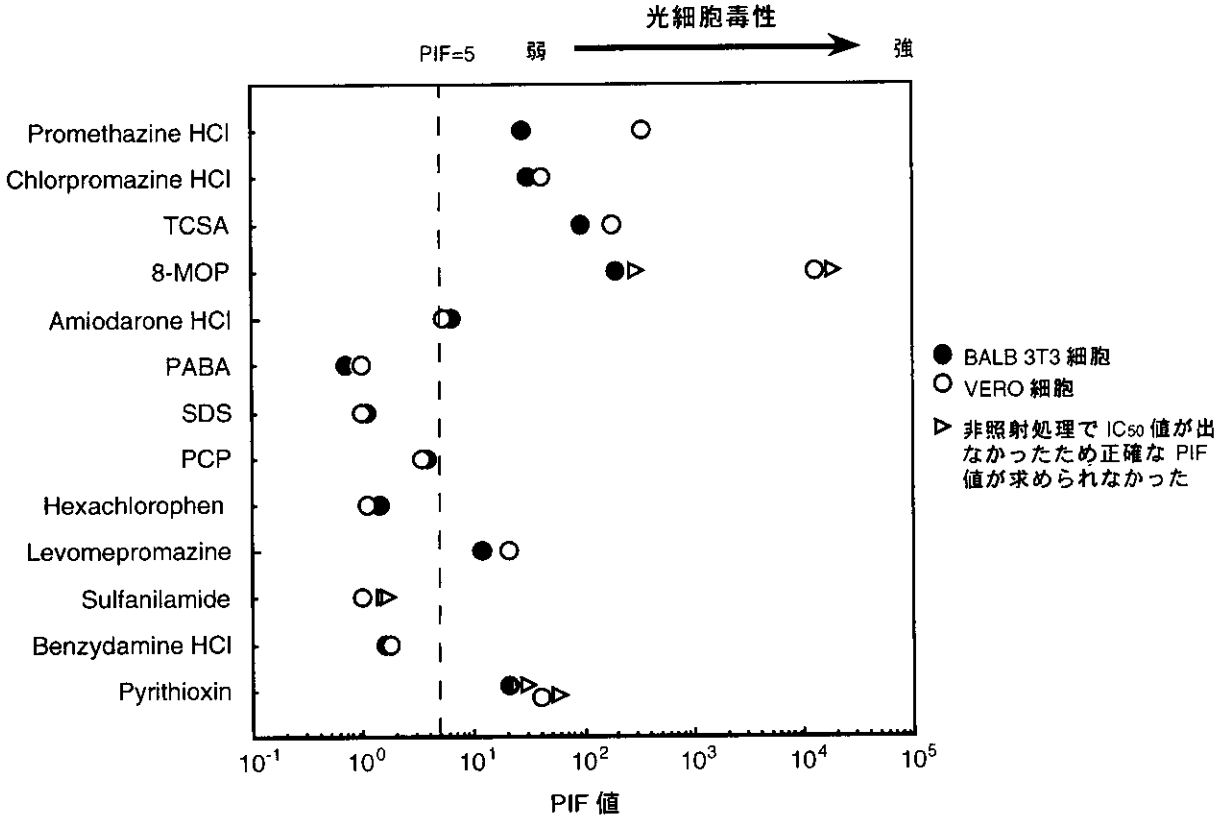

Fig 1　BALB 3T3 細胞と VERO 細胞の NRU PT 法における PIF 値の比較

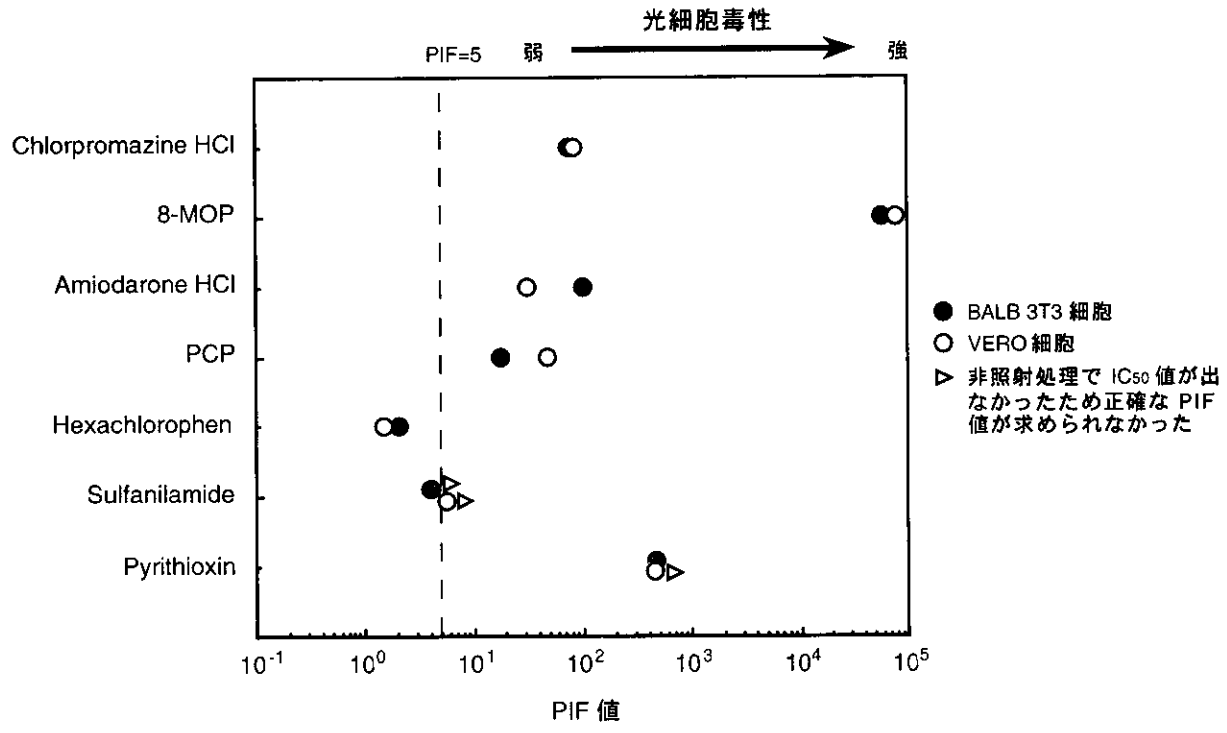

Fig 2　BALB 3T3 細胞と VERO 細胞の CF PT 法における PIF 値の比較

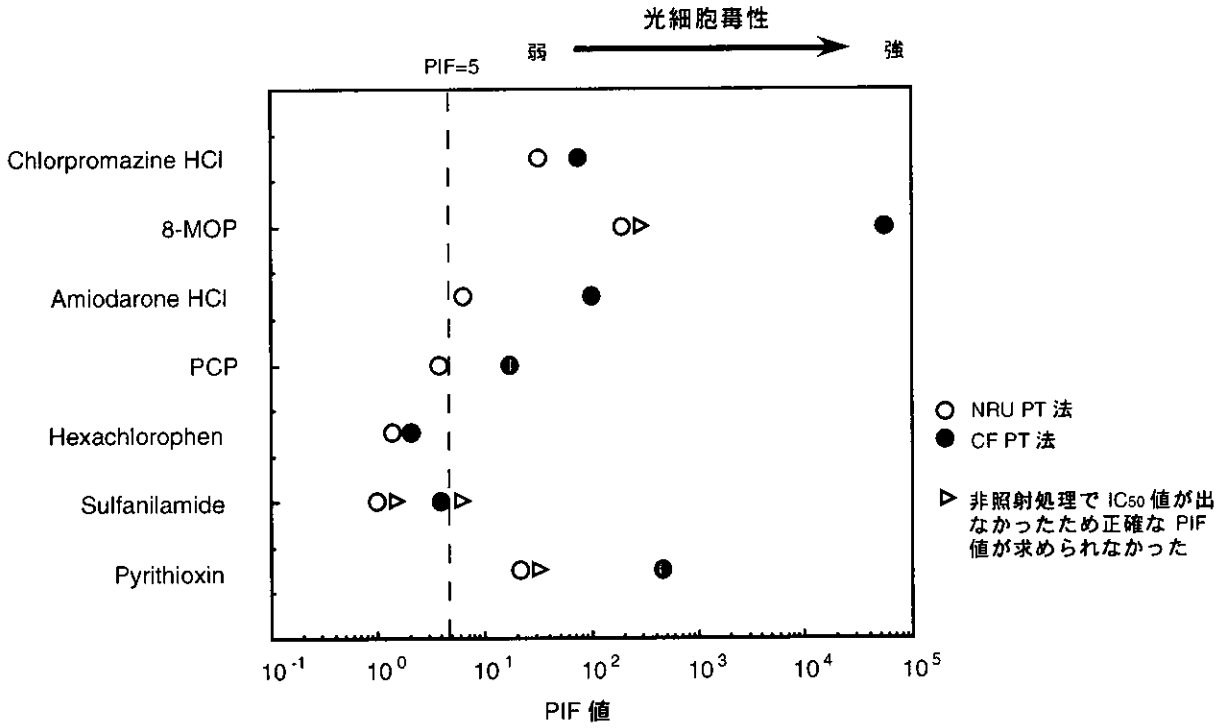

Fig 3　BALB 3T3 細胞の NRU PT 法と CF PT 法における PIF 値の比較

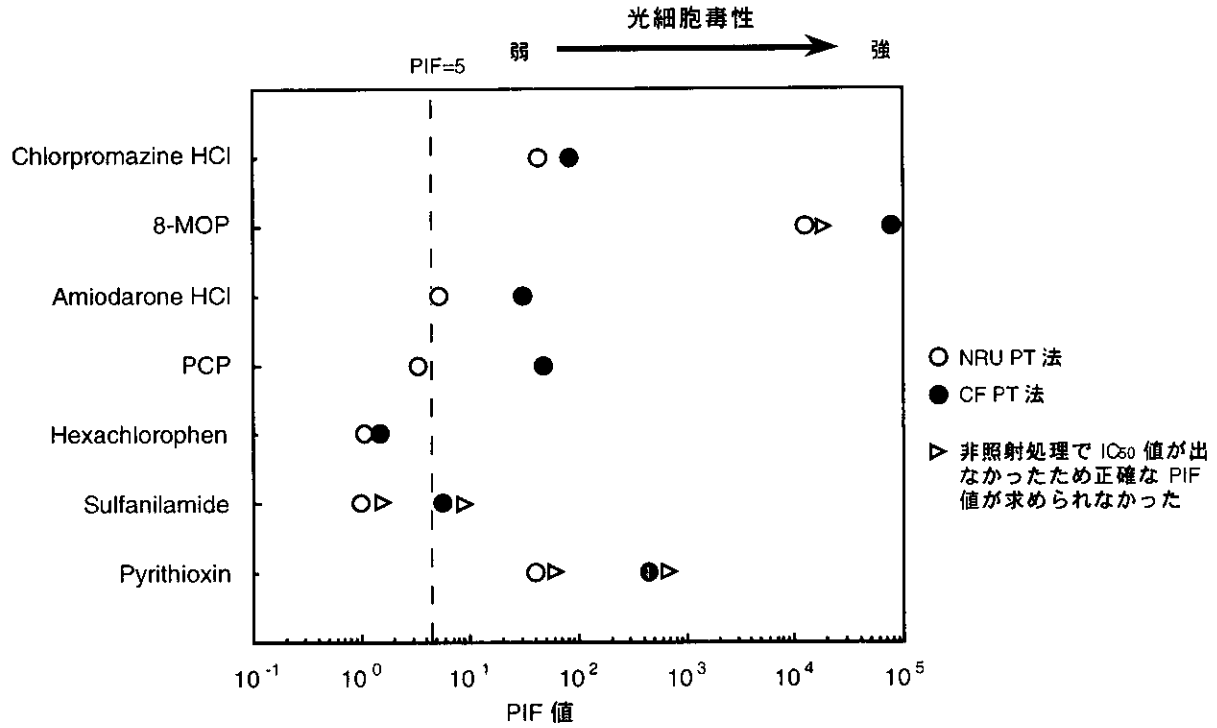

Fig 4　VERO 細胞の NRU PT 法と CF PT 法における PIF 値の比較

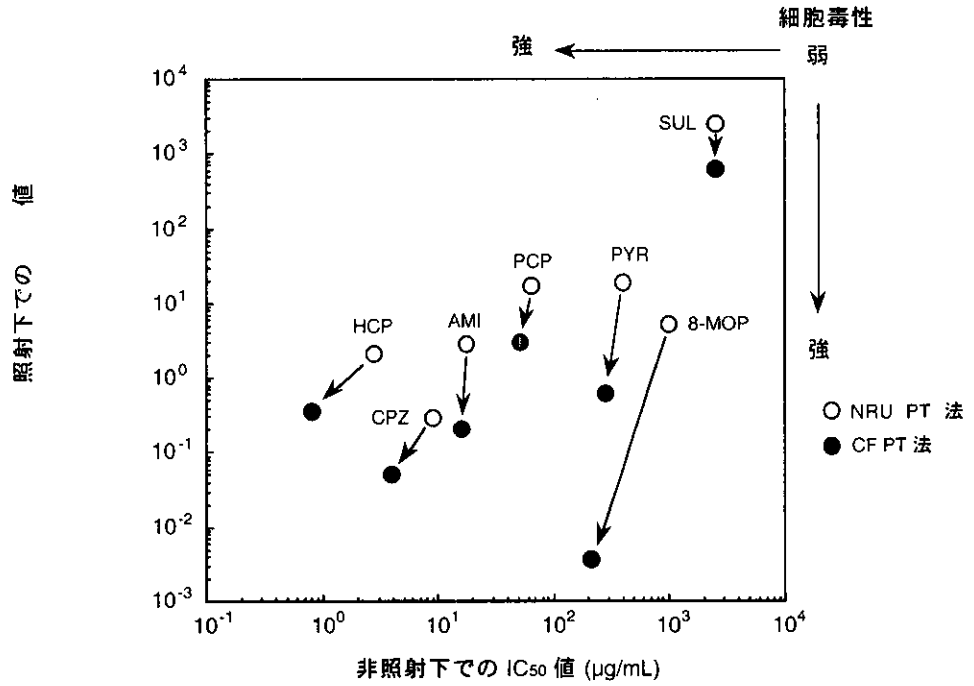

Fig 5　BALB .3T3 細胞の NRU PT 法と CF PT 法における IC_{50} 値の比較

HCP; hexachlorophen, CPZ; chlorpromazine HCl, AMI; amiodarone HCl, PYR; pyrithioxin, SUL; sulfanilamide

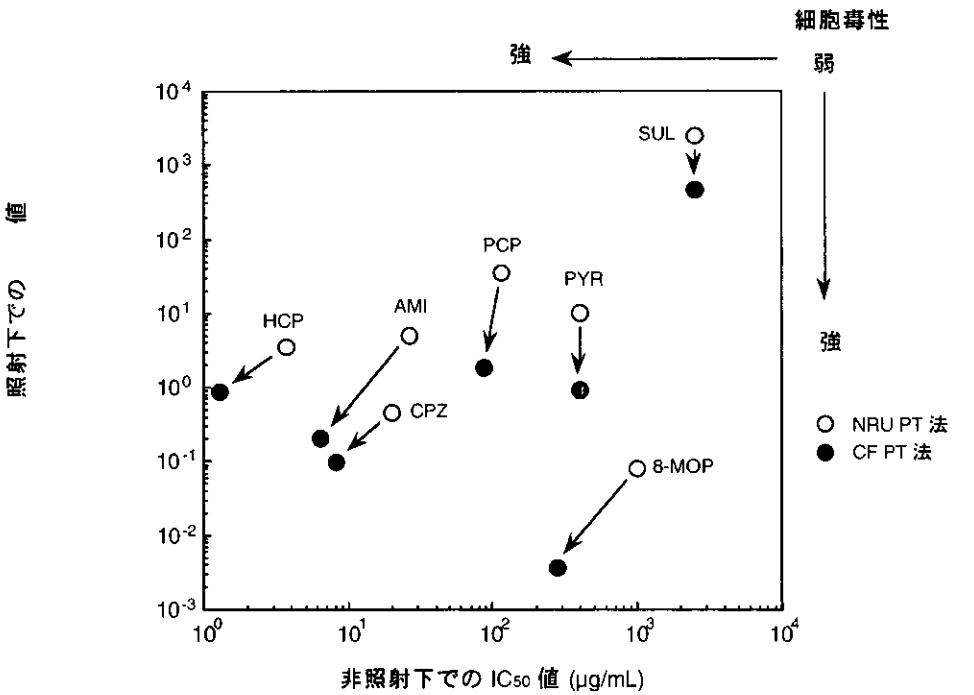

Fig 6　VERO 細胞の NRU PT 法と CF PT 法における IC_{50} 値の比較

HCP; hexachlorophen, CPZ; chlorpromazine HCl, AMI; amiodarone HCl, PYR; pyrithioxin, SUL; sulfanilamide

厚生科学研究費補助金（医薬安全総合研究事業）
分担研究報告書

動物実験代替法の開発と利用に関する調査研究
（代替法についての情報収集と解析、代替法の評価）

分担研究者　豊田英一、日本化粧品工業連合会、技術委員会安全性部会

研究要旨

本年度は動物実験を実施した原料を配合した化粧品の販売禁止を求めるＥＵ化粧品指令第６次改正の最終期限（2002 年６月 30 日まで）を目前に控えていることもあり、ＥＵ化粧品指令第７次改正の動きが従来よりも活発化してきた。米国においても、ICCVAM を中心として代替法に関する報告書の開示とコメント募集があり、長期間に及ぶ動物愛護と代替法開発の努力が実ってきた年度といえる。ＯＥＣＤでは、動物実験代替法の行政的受け入れに関するガイダンスドラフトを作成し、さらには in vitro の皮膚腐食性試験ガイドライン(430、431)や in vitro の光毒性試験ガイドライン(432)のドラフト案及びそれらに対するパブリックコメント募集の案内が 2002 年３月に公開され、代替法の社会的認知の動きが活発化してきた年度といえる。これらの社会的認知の加速は、行政が動物実験代替法の開発や評価に積極的に関与してきた結果と考えられる。

本研究においては、これらの欧米の動向をより密接な情報収集活動により把握し、適切な対応を講じることで、動物実験代替法の開発と利用を促進することを目標に設定し、本調査研究を推進してきた。本調査研究の結果、本邦においても、動物実験代替法の開発と利用を促進するためには、行政の積極的な参加と対応が必要であると考える。

1. 序

本年度は、動物実験を実施した原料を配合した化粧品の販売禁止を求めるＥＵ化粧品指令第６次改正の最終期限（2002 年６月 30 日まで）を目前に控えていることもあり、ＥＵ化粧品指令第７次改正の動きが従来よりも活発化してきた。また EU 動向に連動する形で OECD の動きも活発化してきた。米国においても、ICCVAM を中心として代替法に関する報告書の開示とコメント募集があり、長期間に及ぶ動物愛護と代替法開発の努力が実ってきた年度といえる。本研究においては、以前よりこれらの欧米の動向をより密接な情報収集活動により把握し、適切な対応を講じることで、動物実験代替法の開発と利用を促進することを目標に調査研究を推進してきた。

2. 方法

2．1 情報収集

情報収集は、過去の本研究による経験から、いくつかのホームページ（SCCNFP、OECD、ECVAM、ICCVAM など）を定期的に監視することで行うと同時に EU については同地域の化粧品工業会である COLIPA、米国においては同様に CTFA との連繋を通じて実施した。

3. 結果

3．1 EU における動物実験禁止、代替法開発のの動向

3．1．1 第７次改正

2000 年６月 30 日を期限に動物実験を実施した原料を配合した化粧品の販売禁止を求める EU 化粧品指令第６次改正については、さらに２年間延期する指令（2002 年６月 30 日まで）が公布された [1]。

本年度の進展は、2001 年２月２３日の EU 議会環境委員会での審議、３月 30 日のＥＵ議会の環境委員会での採択を経て、４月３日のＥＵ欧州議会本会議での採択（first reading）が行われた [2]。そこで採択された基本的骨子は、以下の通りである。

- 代替法が存在する場合は直ちに動物実験実施製品の販売禁止。さらに、いかなる場合でもすべての動物実験実施製品の販売禁止を７次改正採択後の５年後とする。
- ７次改正採択時にすでに使用されている成分に関して、採択後に化粧品関連業者以外の者により動物実験が行われた場合は販売禁止とならない。
- 最終製品およびその成分のための動物実験は、代替実験方法がある場合は直ちに、そうでない場合でも 2004 年 12 月 31 日には禁止。

その後、議長国となったベルギーを主体として閣僚理事会で検討され、11 月 26 日に閣僚理事会の票決にかけられ賛成多数で採択された [3]。その後、この法案はＥＵの法律専門家による検討後、2002 年２月１日に「共通の立場」の公式ドラフト案が公表され [4]、２月１４日には公式に「共通の立場」が採択された [5]。次のステップは欧州議会での second reading である。閣僚理事会での採択された「共通の立場」の基本的骨子は、以下の通りである。

- 動物実験を実施した最終製品および原料を含む製品の販売禁止は、代替法として OECD の承認後。
- ＥＵ域内での最終製品の動物実験禁止（法律施行後 36 ヶ月）。
- 代替法が欧州危険物指令の Annex Ⅴもしくは EU 化粧品指令の Annex Ⅸ（新設）に公布された以降のＥＵ域内での原料の動物実験禁止。

3．1．2 小括

ＥＵにおける動物実験の禁止、代替法の開発、Validation の動向は、米国、日本とは全く独立して、自己完結型で進行しているが、一方でこれらの動きは世界をリードするものとしての位置付けもあり、先行した後にハーモナイゼーションに向けての努力を継続していくものと思われる。しかし、今年度は、代替法開発に関しては目立った動きはなかった。

第７次改正の閣僚理事会案では、動物実験を実施した最終製品および原料を含む製品の販売禁止や原料の動物実験は代替法として OECD の承認後となっており、代替法開発における具体的なデッドラインを設けていない。この点で、従来より緩和された産業界側寄りの閣僚理事会案に対し業界の代替法開発の遅延につながるという懸念もあり、ひき続き情報収集が必要である。

この点もふまえ、COLIPA は各社が動物実

験開発研究にどのくらいの金額を投資するかの情報提供依頼などを行い、産業界は代替法開発に力をそそいでいる姿勢を、EUの議員などにアピールする姿勢を示したが、EU 議会の理解を得るまでには至っていない。

3．2　米国における代替法開発の動向

3．2．1　ICCVAM における検討状況

ICCVAM は、米国官庁間の調整を図り共通の目標である代替法の Validation を統括する委員会として機能してきており、現在は NIEHS の恒久的委員会として位置付けられている。本年度は、ICCVAM が関与してきた 3 つの代替法についての報告書の公開とパブリックコメント募集が官報（Federal Register）[6)7)8)]に公表された。

1つが、皮膚腐食性試験代替法に関するものであり、EPISKIN、EpiDerm human skin models、Rat Skin Transcutaneous Electrical Resistance Assay（TER 法）の 3 つの代替法を含む試験法に関するもので、ICCVAM はこれら 3 つの試験法について“integrated testing schema（統合試験体系）”を提案している。即ち、in vitro で陽性反応が出た場合は、更なる試験は不要で、分類と表示（危険物として）に使用できる。しかし、in vitro で陰性反応が出た場合は、in vivo での更なる試験が必要であるとしている[6)9)]。

もう一つは、2000 年 10 月に開催された全身毒性評価の in vitro 法に関する国際ワークショショップの報告書および in vivo での急性毒性試験の初期量設定のための in vitro データの利用に関する指針に関するものである。ICCVAM は、in vivo の急性毒性試験(修正 Up-and-Down 法)と in vitro の細胞毒性試験を併用するとテスト動物数を 30％減少することが可能であると報告している。また、in vivo での急性毒性試験の初期量設定のための in vitro データの利用に関する指針には、データとして利用できるものとして Balb/c 3T3 neutral uptake assay が記されている[7)10)11)]。

もう一つは、急性経口毒性の試験法の一つである修正 Up-and-Down 法に関する報告書に関するものである。この報告書には、ICCVAM による修正 Up-and-Down 法の推奨、第 3 者的立場にいる科学者による評価、最終的なテストガイドラインが含まれている。NICEATM は ICCVAM に代わってこのレポートについての公開のコメントを求めている[8)12)]。

今年もまた、ICCVAM は ILSI Risk Science Institute や EPA とともに、OECD で認められている 3 つの急性毒性試験である、Fixed Dose Procedure，Acute Toxic Class Method、そして Up-and-Down Procedure に関するトレーニングセッションを開催した。このなかには、in vivo での急性毒性試験の初期量設定のための in vitro データの利用に関する事例研究も含まれており、ICCVAM の活動は、単に方法を評価するのみでなく、代替法の日常使用の促進という方向にも目を向けていることが明確になってきた。

3．2．2　小括

米国においては、ICCVAM 主導による代替法の peer review が着実に進行しており、代替法を認定する機関としての位置付けが明確になってきた。ICCVAM は、代替法の評価を目的に、NIEHS とその他 13 の政府研究機関から構成された組織である。ICCVAM の代替法の評価方法は、validation（試験を伴う）を主とする ECVAM とは異なり、これまで得られた結果の peer review である。この方法は、validation に伴う膨大な作業なしに提案された試験法を評価できることから、代替法の社会的認知が促進されるという特徴を持っている。このため、米国では幾つかの試験法に関する peer review が同時進行している。本邦においても動物実験代替法の開発と利用を促進するためには、ICCVAM のような行政主導の組織並びに peer review のような評価方法を検討することは必要と考えられる。

3.3　OECD の動向

3.3.1　ＯＥＣＤガイドラインの動向

これまでにＬＬＮＡガイドライン、in vivo 経皮吸収試験ガイドライン、in vitro 経皮吸収試験ガイドライン、in vitro 光毒性試験ガイドライン、皮膚刺激性・腐食性・眼刺激性試験法のガイドラインについて日本化粧品工業連合会・技術委員会安全性部会で検討し、質問やコメントを全般的なものと個別なものに分けて取りまとめ、厚生科学研究班を通じて、ＯＥＣＤに提出してきた。

2001 年 10 月 30 日～３１日にベルリンで

OECDの専門委員会が開催され、in vitro皮膚腐食性試験ガイドライン及びin vitro光毒性試験ガイドラインに関する検討が行われた。その結果、Rat Skin Transcutaneous Electrical Resistance Assay（TER法）及びヒト皮膚モデル（EipDerm）を用いる試験法については、大枠の合意によりガイドライン430(TER法)[13]及びガイドライン431（ヒト皮膚モデル）[14]のドラフト案及びそれに対するパブリックコメント募集の案内が2002年3月27日にOECDホームページに公開された。

同時に開催されたin vitroの光毒性試験ガイドラインの検討では、韓国、日本および米国のOECD専門委員会の科学者たちが、OECDメンバー各国に対し動物試験と同等の毒性情報を与えるものとして、実験的にバリデートされた動物を使用しない試験であるこの試験をはじめて推奨した。この結果を踏まえ、in vitroの光毒性試験ガイドライン432のドラフト案及びそれに対するパブリックコメント募集の案内が2002年3月15日にOECDホームページに公開された[15]。

急性経口毒性試験に関しては、急性経口毒性試験ガイドライン401の削除を提案してきたが、2001年9月にOECDの委員会のひとつであるEnvironmental Policy Committee(EPOC)にガイドライン401の削除と急性経口毒性試験ガイドライン420(Fixed Dose Procedure)、急性経口毒性試験ガイドライ423(Acute Toxic Class Method)、急性経口毒性試験ガイドライン425(Up-And-Down Procedure)への置換に関するドラフト案を提出した。しかし、その後の審議状況に関する情報は得られていない。

その他の試験法については、現在のところ審議状況に関する情報は得られていない。

3.3.2 ＯＥＣＤガイダンス関連

2002年3月6～8日に、スウェーデンのストックホルムで、有害性評価のための新試験法および改訂試験法のバリデーションと行政的受け入れに関するOECD会議（OECD Workshop on the Development, Validation and Regulatory Acceptance of New and Updated Internationally Acceptable Test Methods in Hazard）が開催された。

この会議の目的は、1996年にスウェーデンのソルナで開催されたOECDの代替法のバリデーションと行政的受け入れの基準に関する会議（OECD Workshop on Harmonization of Validation and Acceptance Criteria for Alternative Toxicological Test Methods ; Solna Report）の結果を踏まえ、行政目的のための有害性評価を目的とした試験法のバリデーションと受け入れに関する基準とそのプロセスについての実際的なガイダンスを作成することである。

具体的な目標としては以下の4項目についての原則と基準の作成があげられている。

- 既存のバリデーション結果の扱い
- バリデーションのプロセスの行い方と運営方法
- 妥当性の確認された試験法の行政的受け入れ
- 新規あるいは改訂試験法の独立したpeer reviewと行政的な検討と実施のプロセス

この会議で合意された結果はOECDのガイダンス“The Development, Validation and Regulatory Acceptance of New and updated Test Methods in Hazard Assessment”に反映される。

3.3.3 小括

OECDは、代替法の行政的受け入れに関するガイダンスのドラフトを作成するとともに個別の試験法に関するガイドラインドラフトも公表したことから、代替法への取り組みが本格化してきたものと考えられる。また、EU化粧品指令第7次改正案においても、OECDガイドラインとの関係が記述されたことから、今後の動向については本研究班では注目していく必要がある。OECD毒性試験ガイドラインは、新規化学物質に適用されることから、本邦においては行政を中心とした産官学による組織的な対応が必要と考えられる。

4. 考察

各結果小括の項で述べた如く、欧米では代替法開発、そしてそれらのガイドライン化に向けValidationやpeer reviewが積極的に進行している。その推進の原動力は、ガイドライン作成に関与する行政の積極的な対応である。EUでは、EU委員会の下部組織であるECVAMが、米国では8省庁の研究機関の連携によるICCVAMが、validationやpeer

review を推進している。OECD ガイドラインは、ECVAM や ICCVAM が個別に認定した試験法をグローバルに波及する影響力を有している。

一方、本邦においては、ECVAM や ICCVAM のような行政主導の代替法評価機関がなく、本研究班が代替法の開発、評価研究と海外情報の調査解析を行っているに留まり、その研究成果はガイドライン作成等の行政的な採り上げまでには至っていない。その結果、OECD ガイドライン化における本邦の提案力も弱くなり、欧米主導の OECD ガイドラインとなってしまっている。

今後の動物実験代替法に関する国際的ハーモナイゼーションを考えるとき、まず最初に手がけるべきは、行政参加の ECVAM や ICCVAM に匹敵する本邦独自の代替法評価機関の設置であると考える。

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13) OECD GUIDELINE FOR THE TESTING OF CHEMICALS: Draft Proposal for a new Guideline:430 In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER) (添付資料－10)

14) OECD GUIDELINE FOR THE TESTING OF CHEMICALS: Draft Proposal for a new Guideline:431 In Vitro Skin Corrosion: Human Skin Model Test (添付資料－11)

15) OECD GUIDELINE FOR THE TESTING OF CHEMICALS: Draft Proposal for a new Guideline:432 In Vitro 3T3 NRU phototoxicity test (添付資料－12)

添付資料－1

Proposal for a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(2000/C 311 E/06)

(Text with EEA relevance)

COM(2000) 189 final — 2000/0077(COD)

(Submitted by the Commission on 6 April 2000)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 76/768/EEC [1], as last amended by Commission Directive 2000/11/EC [2], has comprehensively harmonised the national laws relating to cosmetic products. The main objective of the Directive is to protect public health. To this end it is indispensable to carry out certain toxicological tests to evaluate the safety of cosmetic products for human health.

(2) In accordance with Directive 76/768/EEC, it is essential that the aim of abolishing animal experiments be pursued and that the prohibition of such experiments becomes effective on the territory of the Member States.

(3) The safety of finished cosmetic products can already be assessed from knowledge about the safety of the ingredients which they contain and by methods which do not involve the use of animals. Therefore animal tests with finished cosmetic products should be prohibited.

(4) It will progressively but slowly be possible to ensure the safety of the ingredients and combinations of ingredients used in cosmetic products, at least for the acute effects, without recourse to animal experiments, by using alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative Methods (ECVAM). After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission will have immediately to publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline has to be foreseen, when a definitive prohibition should be introduced. However, the date of implementation of this prohibition should be postponed if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer.

(5) All efforts must be made to ensure that the ethical requirement of animal welfare is recognised world-wide. To this end, the Commission should endeavour to obtain the rapid acceptance by the Organisation for Economic Co-operation and Development (OECD) of alternative methods validated at Community level. Furthermore, in the framework of bilateral agreements with third countries, the Commission should make efforts to obtain recognition of the results of tests carried out in the Community using alternative methods so as not to obstruct the export of cosmetic products for which such methods have been used.

(6) It should be possible to claim on a cosmetic product that no experiment on animals was ever carried out on the finished cosmetic product and/or its ingredients and combinations of ingredients including for the purposes outside the scope of Directive 76/768/EEC. The Commission, in consultation with the Member States, should produce guidelines with the aim of providing clarity and practical guidance to the cosmetic industry, European regulators and above-all the consumer with respect to claims relating to animal testing within the cosmetic sector. These guidelines should aim to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer.

(7) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

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

[2] OJ L 65, 14.3.2000, p. 22.

[3] OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Council Directive 76/768/EEC is hereby amended as follows:

1. Article 4(1)(i) is deleted.

2. The following Article 4a is added:

'*Article 4a*

1. Member States shall take all necessary measures to prohibit the performance on their territory of animal tests in order to meet the requirements of this Directive:

(a) for tests performed on finished cosmetic products (from 1 December 2001);

(b) for tests performed on ingredients or combinations of ingredients, as soon as an alternative method has been published by the Commission, after endorsement of its scientific validity by the European Centre for the Validation of Alternative Methods (ECVAM) and the ECVAM Scientific Advisory Committee, following consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, and in any case (from 1 December 2004). However, if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer, the Commission shall, by (1 June 2004), submit draft measures to postpone the date of implementation of this provision for a sufficient period, and in any case for no more than two years, in accordance with the procedure laid down in Article 10.

2. For the purposes of this Directive, "finished cosmetic product" means the cosmetic product intended to be supplied in its existing state to the final consumer.

3. The Commission shall present an annual report to the European Parliament and the Council on progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals until the entry into force of the prohibition referred to in paragraph 1(b). That report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The Commission shall pay particular attention to the development, validation and legal acceptance of experimental methods which do not use live animals.'.

3. Article 6(3) is amended as follows:

(a) The last sentence of Article 6(3) is deleted.

(b) The following second subparagraph is added:

'Furthermore, the manufacturer or the person responsible for placing the product on the Community market may only take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, of the fact that no animal tests have been carried out provided neither the finished product, nor its prototype, nor any of the ingredients contained in it have ever been the subject of such tests including for purposes outside the scope of this Directive. The Commission, in consultation with the Member States, shall for this purpose publish guidelines on the implementation of this principle.'.

4. In Article 8(2) and Article 8a(3), the title 'Scientific Committee on Cosmetology' is replaced by the title 'Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers'.

5. In Article 9(1), the title 'Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector' is replaced by the title 'Standing Committee on Cosmetic Products'.

6. Article 10 is replaced by the following text:

'*Article 10*

1. The Commission shall be assisted by the Committee.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.'.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than (1 December 2001). They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

CTPA

EUROPEAN UNION

Seventh Amendment to the Cosmetic Directive

On 3 April the European Parliament voted on the Environment Committee report, which comprised the original 20 amendments put forward by Rapporteur Dagmar Roth-Behrendt and a further 45 amendments from members of the Environment Committee. The resultant consolidated amendments are now being considered by the Commission and will be discussed at a meeting of the Council of Ministers Working Group (member states) on 30 April. A further meeting is scheduled for 14 May, the Internal Market Council meeting taking place on 5 June. At this stage it is too early to predict whether the Cosmetic Directive will be on the agenda for 5 June meeting. The proposal being discussed by the Commission and the member states contains the following:

Animal Testing - 'Marketing' Ban

- A marketing ban coming into force immediately where non-animal methods of safety assessment are available and in any case five years after the adoption of the Directive.

- Animal testing conducted after this date shall not invalidate cosmetic products or ingredients already in use within the Community at the date of implementation, unless such testing was conducted by or on behalf of the manufacturer, its agents or suppliers.

- An exemption where testing has been carried out in exceptional circumstances (see below).

Animal Testing - 'Testing' Ban

- Prohibition on animal testing for finished products and ingredients immediately where alternatives are available and in any case by 31 December 2004.

- Exemption for exceptional circumstances where:

- the ingredient is in wide use and cannot be substituted;
- a specific human health problem has been satisfactorily demonstrated.

In these circumstances both the SCCNFP and the European Parliament must agree and the results of tests must be published. Ingredients so tested would be listed in separate annexes to the Directive.

Animal Testing - Claims

- Where a manufacturer has carried out or commissioned animal testing, on finished product or ingredients, or has purchased either from a third party which has carried out such tests, the product must be prominently labelled "tested on animals".

- A product may be labelled as "not tested on animals" (or similar) providing:

- the manufacturer and suppliers have not carried out or commissioned animal tests on finished product or ingredients;
- the manufacturer and suppliers have not knowingly used any ingredients that have been tested on animals for the purpose of developing new cosmetic products by others.

Animal testing - Product Information

- The product information file to include data on any animal testing performed by the manufacturer, its agents or suppliers relating to the development or safety evaluation of the product or its ingredients,

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Seventh Amendment to the Cosmetic Directive (cont)

including any animal testing performed to meet the legislative or regulatory requirements of third countries.

Fragrance

- For the purposes of Article 5 the definition of cosmetic ingredients shall include any chemical substance or preparation of synthetic or natural origin, used in the composition of cosmetic products.
- All ingredients (without the current derogation which allows fragrance ingredients to be collectively labelled "parfum") must be listed.
- 26 specified fragrance ingredients, at levels of above 0.001% in leave-on products and 0.01% in rinse-off products, must be labelled (see comment below).

CMR

- Substances listed in the Dangerous Substances Directive, which are categorised as carcinogenic, mutagenic or toxic, are prohibited unless they have been evaluated by the SCCNFP and found acceptable for use in cosmetics.

Durability Dating

- Where the functions of a product may be affected by deterioration following the opening of the packaging, a maximum period of time for which the product, once opened, will maintain its properties shall be indicated by labelling "once opened, this product should be used within x months".
- For cosmetics with the minimum durability of more than 30 months, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by a symbol and time period.

Children's Products/Intimate Hygiene

- There is a new recital "whereas fragrances should not be used where they do not fulfil an essential purpose, in particular in products intended for children or products for external intimate hygiene".
- The article to which this recital relates requires an exclusive safety assessment for products intended to be sold exclusively for use by children under the age of three and for products intended to be sold exclusively for use in intimate feminine hygiene (see comment below).

Publication of Product Information

- Much of the information currently required in the product information held by the manufacturer would, under a new article, be required to be published in an inventory.

Comment

In addition to the above, there are proposals that the Commission should ensure the development and validation of alternative testing methods and that the Commission should submit a legislative proposal to redefine certain cosmetics as pharmaceuticals. On the other key issues listed above it should be noted that:

- The Commission and the majority of

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Seventh Amendment to the Cosmetic Directive (cont)

the member states currently favour a testing ban to replace the marketing ban. The issue of positive and/or negative labelling claims will depend upon the nature and timing of the animal testing ban.

- It was important that the proposed "can cause an allergic reaction" warning was removed from the proposal at this stage - this is as much a political as a technical issue. CTPA, with the help of many members, lobbied strongly on this point and received good support from UK MEPs. We are delighted that it has been rejected by the Parliament.

- There is an obvious conflict between the amendment which requires all fragrance ingredients to be labelled and the one which requires 26 to be labelled. Hopefully, the Commission and member states will support only the proposal for labelling 26.

- Although the Parliament's proposal on CMRs (the text should refer to reproductive toxins, not simply toxins) is accepted in principle, the 'ban' must only occur after an unfavourable SCCNFP evaluation.

- The durability dating article requires clarification in relation to the time period (currently required as month/year).

- The recital relating to products for children and intimate hygiene appears to exclude the use of any fragrance ingredient whereas the article requires a special safety assessment for such products. Industry supports the latter which should take precedence.

- The proposal for the publication of product information dossiers in the European inventory would not appear to be feasible.

Copies of the text adopted at the European Parliament sitting on 3 April are available from Eleanor O'Connor (eoconnor@ctpa.org.uk).

26th Adaptation to Technical Progress

At the time of writing, no revised draft has yet been issued by the European Commission. We understand that the CATP is expected to be called in May and we would expect to see a new draft prior to that meeting.

WTO Banana Dispute

On 11 April, the European Commission and the US Government reached an agreement to resolve their long standing dispute over bananas. The Commission will introduce a revised method of allocating quotas on banana imports from 1 July 2001 and the US will suspend its sanctions currently imposed on a number of EU exports from that date. The Commission will also propose to the Council and European Parliament an amendment to the Council regulation to

添付資料－3

CTPA *News updates*

Article date: 12 December 2001

Seventh Amendment

On 26 November the Internal Market Council (Ministers representing their member states) voted through the Belgian Presidency proposal for a common position. Germany and Holland abstained, Austria and Denmark voted against, all other member states supported the text. Since it was first issued in mid-October the text has been through four draft stages to accommodate the views of member states. The key elements are:

Animal Testing - 'Marketing' Ban
There is a 'marketing' ban for both ingredients and finished products which is now linked to the availability of validated alternatives. Alternative method is defined in a way which includes reduction, refinement and replacement.

Animal Testing - 'Testing' Ban
The testing on animals of finished cosmetic products within the EU will be prohibited and a cut-off date will be set. The testing of cosmetic ingredients is, like the marketing ban, linked to alternatives.

Animal Testing - Claims
Guidelines will be drawn up by the Commission and put in place via a Commission Directive.

CMRs
The use of CMRs category 1 or 2 will, without delay, be subject to an evaluation by the Commission. Where necessary they will be regulated under Annex II (prohibited) or Annex III (restricted).

Durability Dating
Products to be labelled with a date of minimum durability (ie. a best before date) which will comprise a symbol and a date expressed as month/year or day/month/year. The symbol is still to be agreed.

Fragrance
Fragrance ingredients will be labelled as 'parfum' except those which are listed in Annex III. These will be indicated in the ingredient listing irrespective of their function in the product.

Children's Products / Intimate Hygiene
Article 7(a)(1)(d) now states:

"There shall be inter alia a special assessment for cosmetic products intended exclusively for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene".

Implementation Timing
The text allows 36 months from the adoption of the Directive to the placing on the Community market (ex factory) for compliance. A further one-year is given for sale to the ultimate consumer.

Next Steps
During the next few weeks the Council Text will be studied by the Jurist

Linguist group before being forwarded to the European Parliament as the Council's Common Position. The next step is Second Reading in the European Parliament which is expected to take place in March/April. Members will shortly be asked to make preliminary contact with their MEPs.

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COUNCIL OF
THE EUROPEAN UNION

Brussels, 1 February 2002

Interinstitutional File: 2000/0077 (COD)	15073/01 ADD 1
	ECO 382 CODEC 1332

Subject : **Common position adopted by the Council with a view to the adoption of a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products**

DRAFT STATEMENT OF THE COUNCIL'S REASONS

I. Introduction

1. On 5 April 2000 the Commission submitted a proposal for a Directive based on Article 95 of the Treaty on the approximation of the laws of the Member States relating to cosmetic products [1].

2. The European Parliament adopted its Opinion at first reading on 3 April 2001[2].

3. The Economic and Social Committee delivered its Opinion on 20 September 2000 [3].

4. The Commission presented an amended proposal on 22 November 2001[4].

5. On .... the Council adopted its common position in accordance with Article 251 of the Treaty.

II. Aim

The principle objectives of the Commission's proposal are:

- to introduce permanently and definitively a prohibition on the performance of animal tests for finished cosmetic products in the EU;

- to align the provisions of Directive 76/768/EEC with WTO rules by repealing the provision on a marketing ban, foreseen by the sixth amendment of Directive 76/768/EEC, on cosmetic products containing ingredients or combination of ingredients tested on animals, that would enter into force after 30 June 2002;

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1 OJ C 311 E, 31.10.2000, p. 134.
2 OJ
3 OJ C 367, 20.12.2000, p. 01.
4 OJ

- to introduce a prohibition on the performance of animal tests on ingredients or combination of ingredients for cosmetic products in the EU as soon as validated alternative testing methods are available, accepted and have been published by the Commission but with the stipulation that such a prohibition would become absolute 3 to 5 years after the date of transposition of the Directive.

III. Analysis of the Common Position

1. The Council has been examining the proposal since the middle of 2000. The Council's common position is generally consistent with the aims of the Commission's proposal, in particular as regards compliance with WTO commitments.

   Nevertheless, the Council has agreed on a number of substantial changes to the Commission's proposal. The most important changes are as follows:

   - provisions on a marketing ban on cosmetic products where the final product or its ingredients have been subject to animal testing have been reinstated, while making the implementation of the marketing ban dependent on the existence of alternative testing methods accepted within the framework of the OECD;

   - the introduction of a final cut off date for the implementation of a testing ban on ingredients in the EU has not been included;

   - as requested by the European Parliament, specific provisions on substances classified as carcinogenic, mutagenic or toxic for reproduction have been inserted;

   - provisions on information to consumers have been strengthened also in line with requests from the European Parliament.

   The Commission has accepted the common position agreed by the Council.

2. On 3 April 2001, the European Parliament adopted 31 amendments to the proposal. The Council incorporated, at least in essence, 10 of these amendments and part of 7 others.

3. The Council incorporated part of amendments 1 and 2 that suggest a reference to Council Directive 86/609/EEC on protection of animals used for experimental and other scientific purposes.

4. The Council welcomed amendments 4 and 5 which underline the need to give priority to the support of development of alternative testing methods in particular within the 6th Framework Research Programme.

5. The Council incorporated in general amendment 10 and part of amendment 14 relating to restrictions on substances classified as carcinogenic, mutagenic or toxic for reproduction.

6. The Council incorporated in essence amendments 11, 12 and 30 and part of amendments 23 and 32 which aim at improving labelling requirements in particular as concerns potential fragrance allergens and the minimum durability of the product. The Council incorporated part of amendments 7 and 47 relating to claims by enterprises that no animal testing has been carried out on cosmetic products or their ingredients by a provision stating that the Commission shall adopt guidelines concerning the use of such claims.

7. The Council incorporated part of amendment 14 and amendments 17 to 19 on the Commission's report to Council and the European Parliament while stating that the Commission should forward reports every third year instead of every year.

8. The Council incorporated amendment 26 concerning the reinforcement of the safety assessment of the finished product and in particular the requirement of specific safety assessments for cosmetic products intended exclusively for use on children under the age of three or in external intimate hygiene.

9. The Council considers that it is the prerogative of the Commission to propose an amendment of Directive 86/609/EEC as well as legislation concerning new products and therefore rejected part of amendment 1 and amendment 36 referring to Commission proposals on these subjects.

10. While the Council agrees with the aim of abolishing also animal testing on ingredients for cosmetic products as soon as possible, it considers that this objective should be pursued without compromising the health and safety of consumers. Given the current state of scientific knowledge and the experience gained in the research and development of alternative methods, the Council considers it impossible to predict when all necessary alternative methods, not entailing the use of animals, could be available. The Council therefore favours a stepwise approach linked to the availability of alternative methods, whilst supporting at the same time a reinforcement of the regulatory framework so as to ensure the mandatory use of these methods when they exist, including those which permit a reduction of the number of animals used or a diminution of their pain. However, the Council has underlined that an alternative method which entails the use of animals cannot be accepted when an equivalent method, which does not entail the use of animals, exists. The Council has also considered that the scientific knowledge necessary for the development of additional alternative methods could only improve through the pooling and co-ordination of all resources available. The Council as a consequence rejected part of amendment 2 as well as amendments 3 and 15 relating to the introduction of a final cut off date for totally prohibiting animal testing on ingredients and a limitation of the concept of alternative testing methods to methods that do not entail the use of animals. As a consequence, part of amendment 15 regarding possible derogations from the testing ban was also rejected.

11. By linking the implementation of a marketing ban on cosmetics tested on animals to the existence of alternative testing methods accepted within the framework of the OECD, the Council has struck a balance between the aim of abolishing animal tests in the cosmetic sector and the need to comply with the Community's international obligations, especially in relation to the WTO. The Council therefore rejected part of amendments 14 and 37 relating to a final cut off date for the implementation of a total marketing ban and as a consequence also part of amendment 14 which provides for a possibility to derogate from the marketing ban.