

**UDENRIGSMINISTERIET**

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**KOMITÉSAG**

Til underretning for Folketingets Europaudvalg vedlægges Fødevareministeriets grundnotat om forslag til ændring af Kommissionens direktiv 93/10/-EØF om materialer og genstande af folie af cellulosegenerater, bestemt til at komme i berøring med levnedsmidler, dokument SANCO/2002/10055, EMB/947 Rev. 2.

Forslaget behandles i en III a-procedure i Den Stående Komité for Fødevarerækæden og Dyresundhed.

## **Ministeriet for Fødevarer, Landbrug og Fiskeri**

Fødevaredirektoratet/dep - 6. kontor

J.nr.: 2002-20-221-00204/1997-4839-0001

Den 26. maj 2003

TAJ/DLI/JHC

FVM 055

### **GRUNNOTAT TIL FOLKETINGETS EUROPAUDVALG**

**om forslag til ændring af Kommissionens direktiv 93/10/EØF om materialer og genstande af folie af cellulosegenerater, bestemt til at komme i berøring med levnedsmidler**

**SANCO/2002/10055, EMB/947 Rev. 2.**

#### **Resumé**

*Forslaget vedrører bl.a. en udvidelse af direktivets anvendelsesområde med henblik på at øge muligheden for kompostering og biologisk nedbrydning af fx emballager. Endvidere ændres anvendelsesområdet således, at folier med et lag overfladebehandlingsmiddel på over 50mg/dm<sup>2</sup> på den side, som er i kontakt med fødevarer, ikke længere er undtaget fra kravene i reguleringen. Desuden føjes der i forslaget flere sundhedsmæssigt vurderede stoffer til positivlisten over stoffer, der må anvendes ved fremstilling af folier af cellulosegenerater. Forslaget skønnes at øge beskyttelsesniveauet i Danmark.*

#### **Baggrund**

Kommissionen har ved dokument SANCO/2002/10055, EMB/947, rev. 2, fremsendt forslag om ændring af Kommissionens direktiv 93/10/EØF om materialer og genstande af folie af cellulosegenerater, bestemt til at komme i berøring med levnedsmidler, som ændret ved Kommissionens direktiv 93/111/EF.

Forslaget er fremsat med hjemmel i artikel 3 i Rådets direktiv 89/109/EØF af 21. december 1988 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler.

Forslaget behandles i en III a-procedure i Den Stående Komitè for Fødevarekæden og Dyrer sundhed. Hvis der er kvalificeret flertal, udsteder Kommissionen direktivet. Opnås der ikke kvalificeret flertal, forelægger Kommissionen sagen for Rådet, der kan vedtage forslaget

uændret med kvalificeret flertal eller ændre det med enstemmighed. Handler Rådet ikke inden en frist på højst tre måneder, kan Kommissionen udstede direktivet.

### **Nærheds- og proportionalitetsprincippet**

Forslaget er en ændring af en gennemførelsesretsakt til Rådets direktiv 89/109 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler. Formålet med forslaget er bl.a. at harmonisere beskyttelsesniveauet i EU for at undgå risici for menneskers sundhed. Forslaget vurderes at være i overensstemmelse med nærheds- og proportionalitetsprincippet.

### **Formål og indhold**

Direktivets formål og indhold i hovedpunkter:

1. Ændring/udvidelse af direktivets anvendelsesområde med henblik på at øge muligheden for kompostering og bionedbrydning af folie af cellulosegenerater.
2. Anvendelsesområde.
3. Godkendelse af nye stoffer.
4. Revurderingsforpligtelse.

#### **Ad 1**

På baggrund af et ønske fra industrien om at øge muligheden for kompostering og bionedbrydning af produkter af folie af cellulosegenerater åbnes der med dette ændringsdirektiv op for, at folie af cellulose kan være overfladebehandlet med stoffer listet på Kommissionens direktiv 2002/72/EF om plastmaterialer og -genstande bestemt til berøring med levnedsmidler. Ændringen er således et ønske om at forbedre muligheden for at leve op til kravene i direktiv 94/62 om emballage og emballageaffald. Det gældende direktiv om cellulosegenerater tillader kun anvendelse af de deri listede stoffer til fremstilling af cellulosegenerater (positivliste), og direktiv 2002/72/EF finder kun anvendelse på enkeltlagsmaterialer, hvorfor denne ændring er nødvendig for at regulere kombinationen af de to materialetyper.

Kombinationsmaterialerne skal som følge af ændringen leve op til kravene i begge direktiver. Kontrol med overholdelsen af kravene i direktiv 2002/72 sker iht. kontroldirektivet på plastområdet.

#### **Ad 2**

Hidtil har reglerne i direktivet om cellulosegenerater eksplicit undtaget folier af cellulosegenerater, der har et lag overfladebehandlingsmiddel på over 50 mg/dm<sup>2</sup> på den side, som er i

kontakt med fødevarer. I det foreliggende udkast er folier af cellulosegenerater ikke undtaget, og de er således omfattet af reguleringen i direktivet.

#### Ad 3

Positivlisten i direktivets bilag over godkendte stoffer udvides i overensstemmelse med vurderinger foretaget af Den Videnskabelige Komité for Fødevarer (SCF), dog alene således at nye stoffer tilføjes. Der sker ikke en generel opdatering af bilaget med vurderinger foretaget af SCF. Der vurderes dog ikke at være sundhedsmæssige problemer.

#### Ad 4

Artikel 4a angiver en forpligtelse for Kommissionen til indenfor 3 år efter ikrafttrædelsen af direktivet, at revurdere og opdatere listen over tilladte stoffer på baggrund af nye videnskabelige data og teknologisk udvikling.

### **Gældende dansk ret**

Bekendtgørelse nr. 111 af 20. februar 2003 om materialer og genstande bestemt til kontakt med fødevarer indeholder dels generelle bestemmelser om materialer og genstande, dels indeholder den specifikke bestemmelser om folie af cellulosegenerater, som bl.a. omfatter en positivliste over indhold i folie af cellulosegenerater.

Bekendtgørelsen implementerer EU-direktiver på området materialer og genstande, særligt Rådets direktiv 89/109/EØF af 21. december 1988 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler.

### **Konsekvenser**

Forslaget skønnes at øge beskyttelsesniveauet i Danmark.

Vedtagelse af forslaget vil gøre en ændring af bekendtgørelsen om materialer og genstande nødvendig.

Forslaget skønnes ikke at få statsfinansielle eller samfundsøkonomiske konsekvenser for Danmark.

### **Høring**

Forslaget har i medfør af Fødevarelovens § 6, stk. 1 været sendt i høring til Fødevaredirektoratets høringskreds. Forslaget har endvidere været sendt i høring i Det Rådgivende Fødevareudvalg.

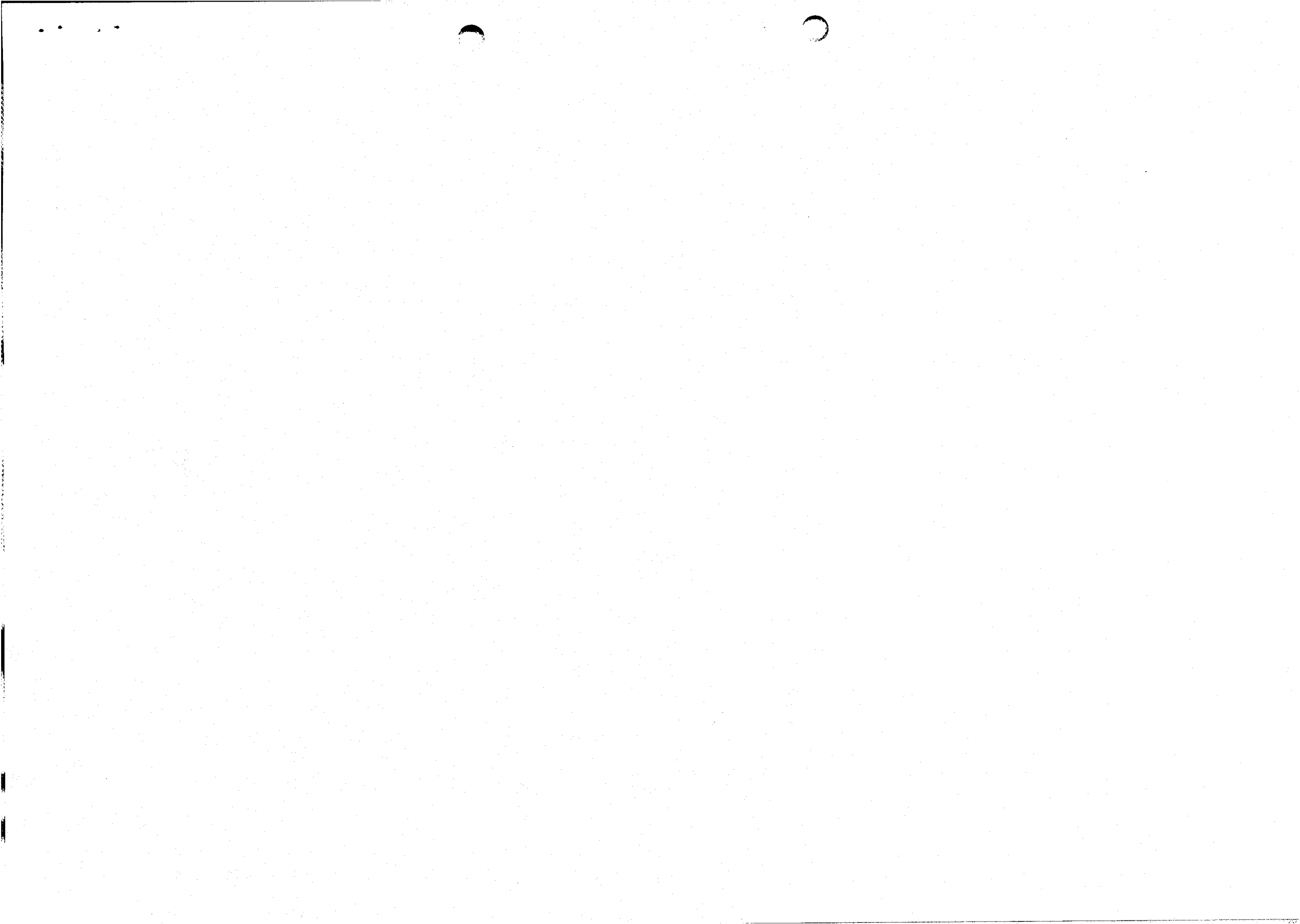
Følgende organisationer har meddelt, at man ikke har bemærkninger til forslaget: FødevareIndustrien, KVL, SiD, Coop Danmark samt Landbrugsraadet på vegne af Dansk Landbrug, Danske Slagterier og Mejeriforeningen.

#### **Tidligere forelæggelse for Folketingets Europaudvalg**

Forslaget har ikke tidligere været forelagt Folketingets Europaudvalg.

EN

SANCO/2002/10055





COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.2.2003  
SANCO/2002/10055

**EMB/947 Rev.2**

**WORKING DOCUMENT:**  
**DOES NOT NECESSARILY**  
**REPRESENT THE VIEWS OF**  
**THE COMMISSION**

**COMMUNICATION FROM THE COMMISSION**

**Explanatory Note**

Draft

**COMMISSION DIRECTIVE ..../EC**

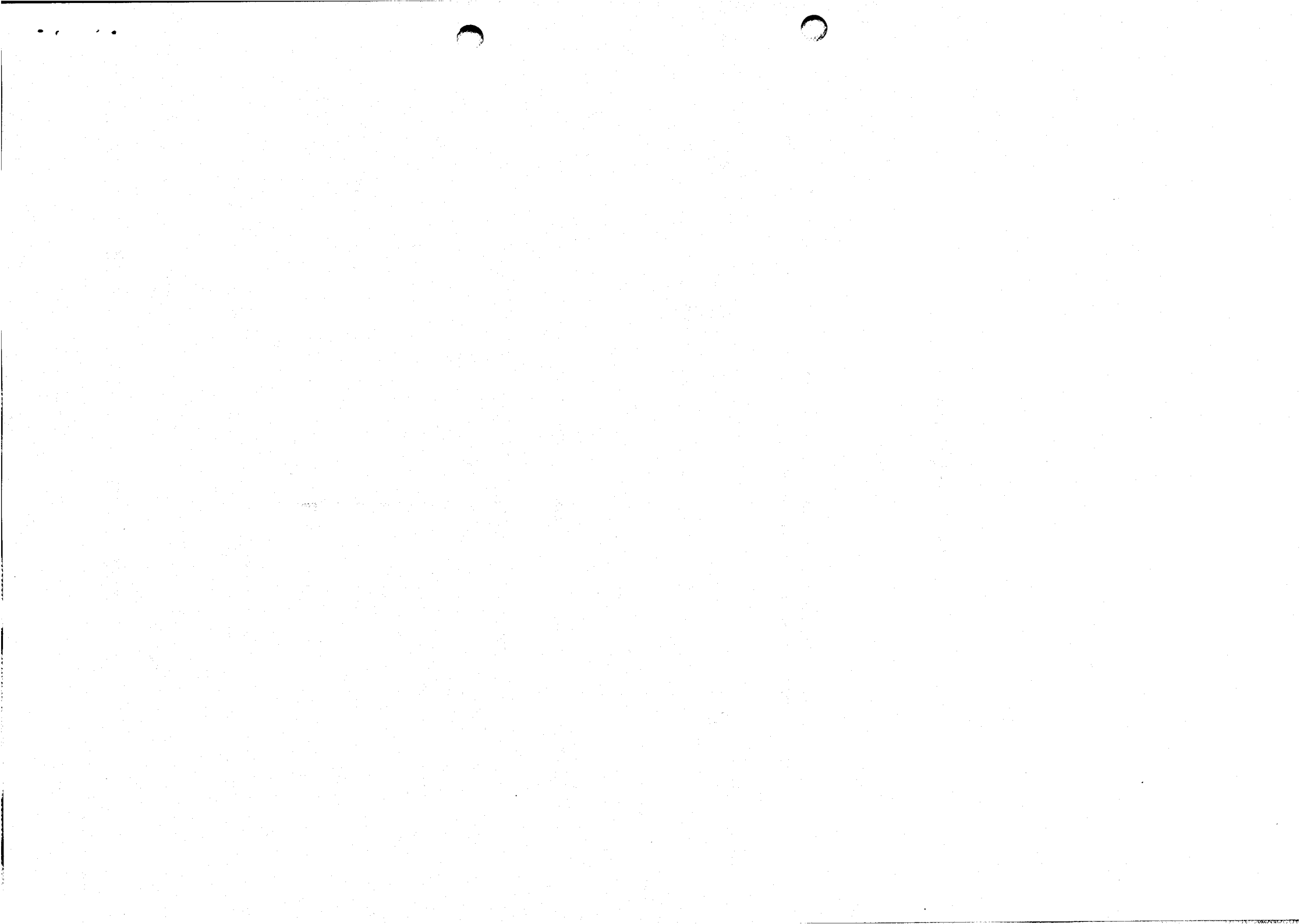
**of [...]**

**amending Commission Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs**

(EN)

(Text with EEA relevance)





# COMMUNICATION FROM THE COMMISSION

## EXPLANATORY NOTE

### 1. BACKGROUND

Commission Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film (RCF) intended to come into contact with foodstuffs establishes a positive list of authorised substances together with their restrictions of use.

This Directive regulates regenerated cellulose films uncoated or coated with coatings manufactured only with substances listed in this Directive.

### 2. NEW ISSUES

#### 2.1 New Compostable Materials

Since Directive 93/10/EEC was in place there have been many technological developments and changes in the market of RCF. These materials are required to have better barrier properties as packaging materials and at the same time to be compostable in accordance with the Packaging Waste Directive 94/62/EC.

The RCF Industry has informed the Commission that regenerated cellulose films coated with coatings derived from cellulose currently regulated by Directive 93/10/EEC cannot be both compostable and give good technical properties. The industry also notified that innovative films that fulfil both requirements have been recently developed, and are coated with polymeric coatings complying with Directive 2002/72/EC on plastic materials and articles intended for food contact. Although safe for the consumer and more environmental friendly, these films are not legally permitted because they are neither covered by Directive 2002/72/EC which excludes multilayer materials nor by Directive 93/10/EEC.

Directive 93/10/EEC needs therefore to be amended to take into account this new type of RCF for reasons of innovation and competition, but also for conformity with the requirements of the Packaging Waste Directive.

#### 2.2 Restrictions and analytical problems

During the consultation in view of the draft amendment, some Member States also requested that the restrictions specified in Directive 93/10/EEC should be revised in accordance with the more recent SCF opinions and they should be consistent with those set in Directive 2002/72/EC.

For the new type of RCF coated with coatings consisting of plastics, this request does not pose a problem because these materials will be required to comply with Directive 2002/72/EC which is based on new scientific opinions. As for the traditional RCF, uncoated or coated with cellulose based coatings, some remarks were made that the restrictions in Directive 93/10/EEC are different from the restrictions set for the same substances in Directive 2002/72/EC. The Commission services therefore made an attempt to examine the problem by

comparing the restrictions for the same substances in Directive 93/10/EEC and Directive 2002/72/EC. It has to be noted that the comparison was not always feasible because:

- The description of the substances is different.
- In Directive 93/10/EEC, the restrictions often apply to a group of substances and not to the individual substances as in Directive 2002/72/EC.
- The evaluation of substances is not based on the same criteria. The technological properties of the RCF uncoated or coated with cellulose do not allow contact with liquid foods. In practice only the contact with solid or semi-solid food should be expected. Therefore, before the first Directive 83/229/EEC on RCF was drafted, the SCF has agreed to endorse restrictions for the finished articles rather than to establish SMLs. The establishment of these restrictions was based on the information available on toxicology, the reduced number of substances used, the restricted use of these materials with foodstuffs, their technological properties and the information on migration into foods .

In this crude exercise the Commission services noticed only some discrepancies in the restrictions and propose to remedy them in this draft Directive. To fully appreciate if all restrictions in Directive 93/10/EEC are in accordance with the recent scientific opinion, a new description of the substances appearing in the Directive 93/10/EEC is necessary. In addition a thorough comparison of their current restrictions with the restrictions of Directive 2002/72/EC is required in order to decide which are the more severe. This exercise is time consuming and requires collection of data and further discussion with the stakeholders.

Another problem raised was the difficulty to enforce the quantitative restrictions for substances laid down in Directive 93/10/EEC, when these restrictions are related only to the coating on the side in contact with food and not to the finished article as a whole. Experimental researches are necessary to establish a relationship between the restrictions when they are related to one side or to the entire finished article.

Finally a Member State claimed that the provisions on colouring matters and adhesives in Directive 93/10/EEC should be also revised with a view to establish positive lists. This question should be debated thoroughly as most of the Member States are not in favour of a positive list.

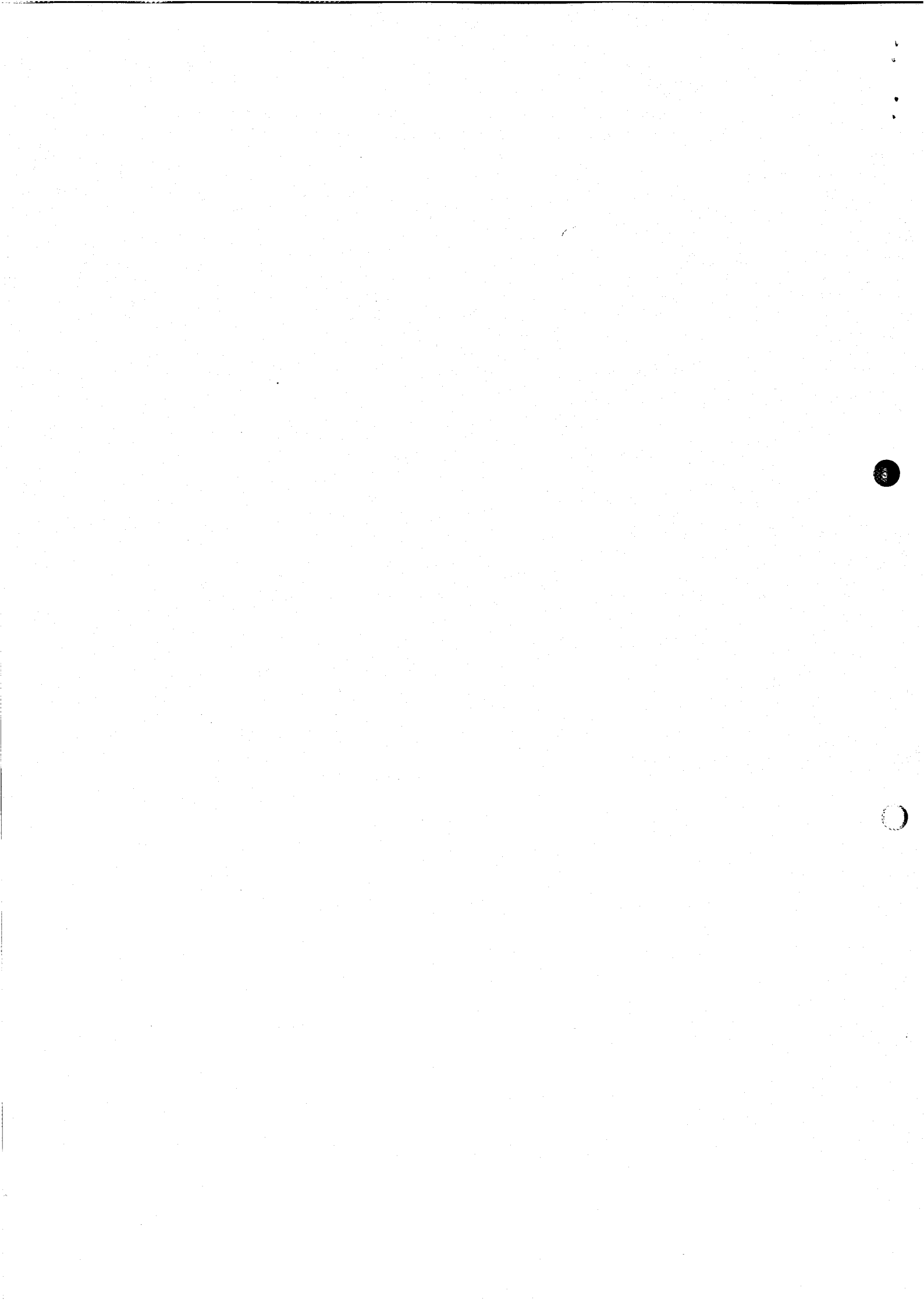
### **3. PROPOSED CHANGES**

The proposed changes aim to include the new type of RCF in the field of application of Directive 93/10/EEC, subject to the requirements of Directive 2002/72/EEC on plastics. These changes will enhance innovation while at the same time will ensure consumer safety and compatibility with the Packaging Waste Directive.

Changes in the legal status of some substances are also suggested in this proposal to remove evident discrepancies between the restrictions of the two Directives.

To take into account the other problems and consider if amendments are needed to the Directive, the Commission will need further time to collect data, to examine the available information and if necessary consult the EFSA. For this reason, no amendments are proposed in this draft Directive in relation to these issues, but a revision clause is inserted that commits

the Commission to review the Directive within 3 years from its entry into force. During this time Member States are invited to advise the Commission of any specific problems that arise.



Draft

**COMMISSION DIRECTIVE ./.../EC**

of [...]

**amending Commission Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs<sup>1</sup>, and in particular Article 3 thereof,

After consulting the "European Food Safety Authority" (EFSA),

Whereas:

- (1) There is need to authorise a new type of coated regenerated cellulose film with a coating consisting of plastics, which is compostable and biodegradable and therefore in accordance with the requirements of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste<sup>2</sup>.
- (2) The rules to be applied to the regenerated cellulose films should be specific to the nature of the layer in contact with the foodstuff and therefore, the requirements for regenerated cellulose films coated with coatings consisting of plastics should be different from those provided for regenerated cellulose films uncoated or coated with coatings derived from cellulose.
- (3) Only authorised substances should be used in the manufacture of all the types of regenerated cellulose films.
- (4) Commission Directive 93/10/EEC<sup>3</sup> of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, as last amended by Directive 93/111/EC<sup>4</sup>, established for uncoated and coated regenerated cellulose films a list of authorised substances, accompanied by strict limits of composition.

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<sup>1</sup> OJ L 40, 11.2.1989, p. 38

<sup>2</sup> OJ L 365, 31/12/1994, p. 10

<sup>3</sup> OJ No L 93, 17.4.1993, p. 27

<sup>4</sup> OJ No L 310, 14.12.1993, p. 41

- (5) In the case of regenerated cellulose films coated with coatings consisting of plastics, the layer in contact with food consists of a material similar to plastic materials and articles intended to come into contact with foodstuffs; therefore the rules of Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs<sup>5</sup> should be applicable also to these films.
- (6) The verification of compliance of coated regenerated cellulose films with coating consisting of plastics, with the migration limits set by Directive 2002/72/EC should be carried out according to the rules laid down in Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>6</sup>, as last amended by Directive 97/48/EC<sup>7</sup>, and Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>8</sup>.
- (7) Some polymers used as coatings are deleted from the list of authorised substances because these types of coatings will be subject to the rules of Directive 2002/72/EC. Four solvents are also deleted from the list because they are no longer used and because new data are available showing a risk for reproduction. Some plasticisers, which are no longer used, are also deleted from the list. In addition some restrictions have been changed to take into account more recent opinions of the Scientific Committee on Food.
- (8) In order to consider whether other provisions need to be amended in the light of new scientific data or technological developments, the Commission should review Directive 93/10/EEC within 3 years from entry into force of this Directive.
- (9) Directive 93/10/EEC should therefore be amended accordingly.
- (10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

1. Article 1 is replaced by the following:

#### *"Article 1*

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 89/109/EEC.
2. This Directive shall apply to regenerated cellulose film within the meaning of the description given in Annex I which either:

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<sup>5</sup> OJ L 220, 15. 8. 2002, p. 18

<sup>6</sup> OJ L 297, 23.10.1982, p. 26

<sup>7</sup> OJ L 222, 12.8.1997, p. 10

<sup>8</sup> OJ L 372, 31.12.1985, p. 14

- (a) constitutes a finished product in itself; or
- (b) forms part of a finished product containing other materials,

and which is intended to come into contact with food or which, by virtue of its purpose, does come into such contact.

**3. For the purpose of this Directive, three types of regenerated cellulose films are considered:**

- (a) **uncoated regenerated cellulose film**
- (b) **coated regenerated cellulose film with coating derived from cellulose**
- (c) **coated regenerated cellulose film with coating consisting of plastics**

**4. This Directive does not apply to synthetic casings of regenerated cellulose."**

**2. In Article 2, paragraph 1 is replaced by the following:**

**"1. Regenerated cellulose films referred to in points (a) and (b) of Article 1(3) shall be manufactured using only substances or groups of substances listed in Annex II subject to the restrictions specified therein."**

**3. The following Article 2a is inserted:**

***"Article 2a***

- 1. Regenerated cellulose film referred to in point (c) of Article 1(3) shall be manufactured, prior to coating, using only substances or groups of substances listed in the First Part of Annex II subject to the restrictions specified therein.**
- 2. The coating to be applied to the regenerated cellulose film described in paragraph 1 shall be manufactured using only substances or groups of substances listed in the Annexes of Directive 2002/72/EC subject to the restrictions specified therein.**
- 3. Without prejudice to paragraph 1, materials and articles made of regenerated cellulose film referred to in point (c) of Article 1(3) shall comply with the provisions of Directive 2002/72/EC with regard to the restrictions set therein, and the verification of compliance with the migration limits".**

**4. The following Article 4a is inserted:**

***"Article 4a***

**Within 3 years of the entry into force of this Directive and in the light of new scientific data or technological developments, the Commission shall review the provisions of Directive 93/10/EEC and propose amendments, if necessary.**

**5. Annex II is amended as set out in the Annex to this Directive.**



## *Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by *[1 year after the adoption of the Commission]* at latest. They shall forthwith inform the Commission thereof.

Member States shall:

- permit the trade in and use of regenerated cellulose film which is intended to come into contact with food complying with this Directive, from *[.....same date as in the first paragraph of this Article]*,
  - prohibit the manufacture and importation into the Community of regenerated cellulose film which is intended to come into contact with food and which does not comply with this Directive but did comply with Directive 93/10/EEC, as from *[.....same date as in the first paragraph of this Article + 1 year]*,
2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

## *Article 3*

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

## *Article 4*

This Directive is addressed to the Member States.

Done at Brussels, [...]

*For the Commission*

*[...]*

*Member of the Commission*



~~vinyl chloride and vinyl acetate~~  
copolymer based coatings

(d) The following plasticisers are **deleted**:

Denominations	Restrictions
- Butylbenzylphthalate	Not more than 2,0 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs
- Di-n-butyl phthalate	Not more than 3,0 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs
- Di(2-ethylhexyl) sebacate [=dioctylsebacate]	

(e) For the following substances the content of column 'Restrictions' is replaced by the following:

Denominations	Restrictions
- 2-ethylhexyl diphenyl phosphate	Not more than 2,4 mg/6 dm <sup>2</sup> of the coating on the side in contact with foodstuffs

(e) The following solvents are **deleted**:

Denominations	Restrictions
- Ethyleneglycol monoethyl ether	
- Ethyleneglycol monoethyl ether acetate	
- Ethyleneglycol monomethyl ether	
- Ethyleneglycol monomethyl ether acetate	