JUN 28 1972

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June 22, 1972

To: SPI Food, Drug and Cosmetic
Packaging Materials Committee

Re: GRAS Comments and Dutch Regulations for Food Additives

Gentlemen:

In our recent GRAS comments we proposed that incidental additives, with certain exceptions such as heavy metals and the like, should be considered GRAS if the migration of such additives was sufficiently low (we proposed .5 parts per million as the cut-off point). It is interesting, that shortly after we filed these comments, we received through the very great courtesy of Dr. J. H. DeWilde of Shell in The Hague an amplification and more detailed explanation of the Dutch "new look" in food packaging regulations which, in effect, seems aimed at achieving a very similar end result.

You may recall that at our last meeting Bob Miller of Hercules reported on the new Dutch proposals for dealing with the question of incidental food additives. A summary of Bob's presentation was sent to Dr. DeWilde and he has very kindly sent to us a copy of his letter to Bob Miller which amplifies and clarifies the Dutch "new look."

Not only are we being provided with Dr. DeWilde's very careful explanation of the thinking that went into this "new look," but he also included copies of a paper which was presented in Rome by Dr. D. G. Aldershoff which also discusses the "new look." Included with Dr. Aldershoff's paper are two attachments--Annex A which is a sample regulation for polystyrene

(in English translation), and Annex B for glass and glass-based ceramics (in French).

As you review the enclosures you will note that the Dutch government is directing its concern to the quantity of a substance that might actually migrate to a packaged food--not to how much is put into the packaging material. In order to be practical and minimize unnecessary work, the government arbitrarily set a figure of 60 (mg/day, ppm)[1/] as the maximum amount of any indirect additive (except selected plasticizers) that will be permitted to enter the food of an average consumer regardless of how safe or inert it might be.

Based upon toxicological testing on animals and the use of appropriate safety factors, a packaging acceptable daily intake (PADI) is established for each substance permitted in a packaging material and a list of substances with its PADI is prepared. Any substance whose PADI is in excess of 60 mg will require no special considerations; but each substance whose PADI is below 60 mg will require specific analytical attention.

The entire process requires that gross migration tests be conducted with food-simulating solvents. If the total amount extracted is less than 60 mg/5 dm^2 (or 6 dm^2)[2/]

[1/] Dr. DeWilde explains why 60 ppm in the gross extraction test is also equivalent to 60 mg/day intake of extractives. It should be noted, too, that this reduces to 24 ppm in the whole diet, based upon the reasonable assumptions which were used.

[2/] The maximum total surface of packaging material that might reasonably contact the total daily food intake of a consumer has been estimated by the Dutch to be 5 sq. decimeters, and by EEC personnel to be 6 sq. decimeters. In any case, the numerator then represents the maximum quantity

then no specific tests will be required for any component whose PADI is above 60 mg, since the PADI of these substances cannot have been exceeded. However, those components whose PADI are below 60 mg must be given specific analytical attention; and no such substance may be present in an amount (in mg/5 dm^2) that exceeds its PADI.

Even this amount of work may be minimized in some cases, since no specific tests are required for any substance whose PADI is above the gross extractives that are actually found.

Finally, a modification of the Frawley doctrine is included in the scheme because additives migrating to an extent less than 0.05 mg/5 dm^2 are exempted even though no toxicological data is available (unless government toxicologists consider that the structure makes such substances suspect).

There can be controversy about some of the details of this "new look," indeed there is a difference of opinion between Dutch and EEC personnel regarding whether the area used for calculating migration should be 5 dm^2 or 6 dm^2; but the entire approach appears to us to be the result of considerable study. It very carefully balances toxicological considerations against the amount of an additive that might enter the diet. It requires careful (and expensive) analytical work only for those cases where a health hazard could conceivably exist and would seem to signal a constructive move away from the devotion of time, effort, and money to those cases where there is no health problem.

2/ (cont'd) of total extractives that could enter a person's diet if everything he ate that could be packaged were packaged in the material being considered.

While the adoption of a scheme such as the "new look" by the FDA would require a more extensive revision of the American regulatory scheme than seems politically possible in the near future, it is good to note that this very careful blending of law, science, and common sense is being implemented somewhere.

The only thing missing from the information we now have, and by this copy of this letter we are requesting Dr. DeWilde to please send us such additional information if he can do so, is an understanding of how new materials will be added to the Dutch regulations. In other words, what procedure should be followed if a manufacturer, supplier, or user wishes to have a new material added to the list in an existing regulation?

Here in the United States, as you all well know, the petition-regulation procedure is quite complex and extremely time consuming; thus, it would be most interesting and valuable to us to learn how the Dutch are planning to handle this aspect of the regulatory problem.

We hope you find this information as interesting as we did, and that it will prove to be a valuable guide to contemporary European thinking and practice in this area. If you have any questions or comments, please do not hesitate to contact us.

Cordially yours,

Jerome H. Stockman

Enclosures

9th June, 1972

Dr. R.M. Miller
Chairman of the SPI
Food, Drug and Cosmetic Packaging
Committee
c/o Hercules Inc.
910 Market Street
Wilmington (Del) 19899
U.S.A.

Dear Bob,

Somebody forwarded to me a copy of the summary of the speech you gave on the occasion of the SPI's Food, Drug and Cosmetic Packaging Committee's meeting in the Shoreham Hotel on March 15th, 1972.
In offering a few comments I would like to start with complimenting you with the excellent way in which you summarized the Dutch "new look".

The new approach has not been invented merely to resolve the differences between the Latin and the German philosophy but in the first place because the old system is not susceptible to any control. In some countries such as the U.S.A., industry might be so lawful that every company will strictly adhere to the FDA-regulations, but one cannot assume that this ethical behavior is common to industry in every country.

Our "new look", moreover, is directly correlated with the aspects of public health. Technological aspects which were a strong point in the old approach, have been omitted as much as possible, the philosophy being that the Government should not interfere with industry and the way industry wants to formulate food packaging compositions. Allowing 0,2% of a certain additive in, say, PP has no correlation whatsoever with public health since the amount of the additive migrating into the packaged foodstuff depends to a very large extent on the composition of the PP film, its crystallinity, whether stretched and/or coated or not, etc.
The "new look" specifies: on account of public health considerations we don't want more than x mg per day of this additive to be ingested by the average Dutchman.

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Industry is free to use any quantity of that additive in their PP film, but they are responsible for ensuring that not more than x mg is consumed per day per person. The figure "x" is related to the "no-effect level" found in animal tests. Since 2-year tests with rats are needed to establish an ADI (FAO/WHO suggestion) and the Netherlands Government for obvious reasons agreed that 90-day feeding tests would suffice in the case of additives used in food packaging materials, we have denominated "x" as PADI (Packaging ADI).

The only thing which is needed to make the "new look" work is to establish a PADI for each of the additives used and to develop analytical methods to assess quantitatively the specific migration of each migrating additive in foodstuffs. The first part has been accepted by the Council of Europe. The British Government representative, Dr. P. Elias, insisted on establishing PADI's for each additive and Dr. G.J. van Esch (Dutch) has been charged in making "toxicological data-sheets" for each additive. He finished his commitment just before this month's meeting of the Council of Europe and will request the toxicologists of the other countries to fill in the gaps.

The second part, the search for analytical methods is actively being pursued by analytical groups in the various countries. Several of the 24 communications given at the Rome symposium dealt with this subject. All what has been said and done in Rome has been collected and will be printed in one volume. We have already been requested to indicate the number of copies we would lik to purchase but no price has been indicated as yet.

There is one other thing that has worried me for the past few years and that seems near a solution now. The correlation between PADI and the amount of migrated additive (expressed in mg per dm^2) has never been laid down. One of the reasons to accept 90-day animal feeding tests has been the Government assumption that the additive might be used in all packaging materials coming in contact with our daily food. This was assumed to be 5 dm^2 per day (Council of Europe 6 dm^2; Germany 10 dm^2, U.S.A. 30 dm^2). There obviously may be a difference in migration into aqueous and into fatty foodstuffs. Taking this into account would involve a system of "food factors"

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which, however, is less suitable for harmonisation. We therefore suggested quite recently to abandon "food factors" and to multiply the number of mg per dm^2 of migrants with six.

Food simulants are used: distilled water, 3% acetic acid, 10% ethanol and arachis oil, coconut oil or the Unilever synthetic fat HB 307.
Conditions of temperature and time should be chosen as closely as possible approaching actual conditions. Since it has been demonstrated that the migration approaches the asymptote in 6 - 8 days, the testing period not necessarily should exceed, say, 10 days. The French law still demands 30 days; even the not yet published new "directive for applying approval etc.".

To limit the amount of work, the arbitrary number of 60 has been accepted. To the French and Italians this means the limit where above the food will be considered contaminated. To the Dutch it means that no PADI has to be calculated of additives that can be consumed in larger quantities than 60 mg per day. There consequently is no need for policing these as long as the "gross migration" is lower than 60 mg per 5 dm^2 (6 dm^2).
In the case of plastics this is always so except for plastics containing plasticizers. A total quantity of 100 ppm of defined plasticizers on the packaged food parcel is allowed. Whether this figure will be maintained in the future remains to be seen since plasticizers may not be always that safe. Additives migrating less than 0,05 mg per 5 dm^2 are exempted (Frawley doctrine) even although no toxicity data are known (except when their structure seems suspect to our Government toxicologists).

The figure of 5 dm^2 (6 dm^2 to follow the Council of Europe's advise) has been accepted as the average surface coming into contact with the 1 kg non-dry packed food consumed daily per person.

./. Please, find attached the communication Dr. Aldershoff submitted at the Rome symposium. Included as annexe "A" is the English translation of schedule 2: polystyrene mixed and copolymers. You will note that only a few additives have to be policed which makes the whole scheme workable. The control laboratory will first make a qualitative analysis of the packaging material to assess which additives are present and whether the

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composition complies with the "positive list". Only for reasons of easier control we adhere to separate lists for each separate type of plastics - otherwise one could accept the alphabetical Italian list.

B.I.T.M.P. and S.I.I.C. are making an attempt to convince the Council of Europe that a) monomers are different from additives in that they are reactive and their presence in the end-product can be expected in exceptional cases only that can be listed or regulated;
b) process chemicals are used in small quantities, will partly break-down or combine with the polymer so that their specific analysis in the migrate is not needed.
If Governments want to play safe, analysis of groups (e.g. peroxides) or heavy metal traces can be incorporated.

Annexe "B" shows that the same system works with glass. We have almost finalized paper and board, elastomers, glass, ceramics, metals and are now working on a "coating list".

I cannot support your statement that the Netherlands' "new look" will not be of much help to you in your negotiations with FDA. In contrary, this "new look" may offer you an unique opportunity to get your FDA system changed and simplified, to the benefit of both public health and industry!

I apologize if I have not been able to make the essentials of the "new look" clear in this letter; a personal discussion would be much more efficient.
Do you plan to visit the Netherlands in the near future?
Please, let me know.

With kindest regards,

cordially yours,

cc.: Mr. J.H. Heckman, Washington, D.C., U.S.A.
Ir. M.C. Dieleman, Hercules N.V., The Hague

The New Look of the Dutch Regulations for Packaging Materials, etc. for foodstuffs and Proposals for the Control of End-products.

by Drs. W.G. Aldershoff
presented on behalf of the Dutch Delegation.

I. The New Look of the Dutch Regulations for Packaging Materials, etc. for foodstuffs in order to decrease the analytical burden for controlling the end-product.

A. The main purpose of the Regulations

The main pint of the reglementation which is in The Netherlands in preparation at present for packaging materials, utensils, etc. that come into contact with foodstuffs, is that the health of the consumer of the foodstuff is not hasarded as a result of this contact, more especially as a result of the migration of substances from the packaging materials, etc. into the foodstuffs.

B. The "old" system

In order to effect the purpose mentioned for the various kinds of materials from which packaging materials, etc. are being made (plastics, ceramics, glass, etc) the components or addititves which may be used for its fabrication have been listed on a so-called "positive list".

In principle an additive or component was placed on the list if migration data and results of toxicological investigations led to the conclusion that its use would not be harmful to human health. Of many compounds the results of toxicological investigations were such that a "maximum level of use" - expressed in " % - weight of the additive in the composite material"-had to be prescribed (also mentioned in the list) in order to prevent that as a result of a "too large migration" - larger than corresponding with the A.D.I.[1)] of the additive - human health might be affected.

The migration data which were made availabel in order to enable the decision of whether an additive could be accepted on the list or not, mostly referred to - or: were restricted to - tests on a sample of the packaging material of only one specific composition

1) "A.D.I.": acceptable daily intake.

- often a sample manufactured in the laboratory. Such samples not necessarily have the same properties as the material, that is made in the plant and used in actual practice.

Another aspect of the old system is, that for various compounds different "maximum permitted levels of use" had to be prescribed according to the type of material in which the relevant additives were used, because the migration of the compounds appeared to be different for the different materials.

As to the height of the "maximum permitted level of use": this was generally fixed at the value at which the additive was used in the sample sent in for testing, even if toxicological data would have permitted a higher value.

These old regulations involve a tremendous amount of time-consuming labour-intensive analytical work as regards the control of the end-products.

In the first place becuse of the large number of additives for which a maximum permitted level of use had to be fixed (more than 200 compounds), but also because the isolation of the additives often requires different analytical techniques according to the nature of the material in which they are used.

C. The New Look

Circa half a year ago this system has been abandoned. Two main modifications have been introduced.

The first Modification

The "maximum permitted level of use" is not mentioned anymore on the list.

From toxicological data - mostly obtained from animal feeding tests lasting 90 days using safety factors varying from 100 - 500-it has been calculated how much of the compound may on an average be taken in by a person of 60 kg daily. This quantity, expressed in mg, may referred to as "Packaging A.D.I" or "P.A.D.I.", and has been converted into a maximum permitted level of migration of the compound from the packaging material or article expressed in mg/5 dm^2 or mg/1 of simulant.[1)]

[1)] The following assumptions were made for this conversion: An adult person consumes daily 2.5 kg food, consisting of 1 kg liquids and 1.5 kg "solid" foodstuffs. Half of the 1.0 kg liquids is packed. The liquid that daily is taken in thus has a net contact area with packaging materials of 2.75 dm^2. (An "1-l-bottle"has an inner surf

This maximum permitted level of migration is now indicated on the n w version of the lists of permitted substances instead of the "maximum permitted level of use". See the Annexes A and B for polystyrene mixed and copolymers and glass.

The second modification

In order to reduce the amount of control work a second modification has been introduced consisting in the fixation of a limit for the gross migration.

For the time being the height of the limit has been fixed at the level that in meetings of the Council of Europe (P.A.) has been proposed as limit for the permissible contamination of foodstuffs by migrating substances, namely 60 mg/kg of foodstuff in direct contact with the material or article.

This involves that no specific migration tests have to be made anymore of substances with a P.A.D.I. (maximum permitted migration level) below 60 mg/5 dm^2 or 60 mg/l.

In general the number of tests to be carried out will be smaller: of no other substances the (specific) migration has to be exami ed than those with a P.A.D.I. smaller than the values of the actual gross migration found during testing.

D. Advantages of the new system

1. The new version more clearly expresses that the reglementation is intended to safeguard public health: it simply mentions how much is maximum tolerable in the foodstuff as a result of migration leaving it to the manufacturer how to make the product and to meet the reguirements regarding migration.
2. The amount of analytical work is considerably reduced as compare with the old version.
3. The fixed "maximum permitted level of migration" or P.A.D.I. for a certain compound is valid for all packaging materials in which the relevant additive is used.

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cont. [1] Half of the 1.5 kg solid food is packed but half also consists o dry foodstuffs in which no migration is expected. The result is that 0.375 kg of the daily solid food has a contact area with packaging materials of 2.25 dm^2. (1 kg of solid non-dry foodstuff is packed in 6 dm^2 packaging material).
The overall result is that of the 2.5 kg daily diet circa 1 kg is contact with packaging materials in such a way that migration may occur.the net contact area amounting to 5 dm^2.

II. Proposals for the control of end-products

In the foregoing it has been explained that packaging materials, utensils etc. coming into contact with foodstuffs have to meet certain requirements regarding

a. the use of permitted additives during manufacture
b. gross migration
c. the migration of specific components.

The control as to whether these requirements are met or not must therefore comprise the following tests: (See Annex C)

A. Composition analysis

Main purpose: determination of the qualitative composition of the product

B. Gross migration test

Main purpose: check that the 60 ppm limit is not surpassed and determine for which additives a "specific migration test"is nee

C. Specific migration test

Main purpose: check on the migration of volatile compound and of additives for which a P.A.D.I. has been fixed.

Regarding these three tests the following annotations are made:

A. Composition analysis

This analysis in the first place serves to check whether no other additives or constituents than those that are permitted have been used. Furthermore it serves to provide information on the presence of

a. substances for which a P.A.D.I.has been indicated in the rel vant list
b. volatile substances.

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cont. 1) The above figures may vary somewhat in accordance with variatio in daily diet from country to country, but calculations show that the variations in the figures are minor only.
The above is based on the starting point that for the judgment the migration of a component from a packaging material it is assumed that the packed foodstuffs of the daily diet are all packed in this material only.

This information is necessary in order to know for which substances specific migration tests must be made (see the relevant paragraph).

B. Gross migration test

a. Food Simulants and temperature and time of test

From technical-analytical considerations it very rarely is possible to make gross migration tests in the foodstuffs proper under conditions of actual use.

The actual controlling tests replacing the tests in the foodstuffs under actual conditions of use should, however, be carried out under conditions that simulate the actual conditions of use as much as possible.

This involves a proper choice of

1. food simulants and of
2. conditions of temperature and time for the test.

1. Food Simulants

Apart from dry food, foodstuffs may roughly be divided into aqueous, acid, alcoholic and fatty foods.

For these categories the following Food Simulants have been proposed:

distilled water	for aqueous foodstuffs
3 % acetic acid	for acid foodstuffs
10 % ethanol	for alcoholic foodstuffs
triglyceride(s)	for fatty foodstuffs

As regards the simulants to be used during tests:

if the material or article to be tested is destined for one single use or purpose only (e.g. for contact with oils and fats only) it is sufficient to do the testing with the relevant simulant only

if, however, no special purpose or use is indicated testing has to be carried out with all four food simulants.

2. Conditions of Temperature and time during migration tests

It seems appropriate to distinguish between

1. materials etc. that are used only once and after use are thrown away
2. utensils, objects etc. like dishes, cups, plates, pans and kitchen utensils, soft drink bottles and milk bottles, that are used repeatedly.

1. Materials used only once

The conditions of contact with foodstuffs vary considerably in temperature and time.

In the scheme below the following five main temperature ranges have been distinguished:

1. A low temperature range: up to + 5°C
   (incl. temperatures applied in the manufacturing and storage of quick frozen products)
   proposed test temperature: + 5°C.

2. Room temperature
   proposed test temperature: 40°C

3. Temperatures between 70°C and 100°C
   These temperatures occur during pasteurisation processes hot filling of products like jams and marmelades, in the household (soup-tureens) etc.
   proposed test temperature: 100°C.

4. Temperature of 120°C
   This temperature occurs during the sterilization process.

5. Temperatures of 150°C - 175°C Films used during baking foods in ovens are exposed to these temperatures.

The proposed test temperatures and times are very close to those that are already being applied or have already been proposed in several countries.

Conditions of temperature and time in actual practice		simulating conditions to be used in tests	
temperature	time	temperature	time
up to + 5°C	max. a few months	5°C	10 days
room temperature	max. a few months	40°C	10 days
70°C - 100°C	relatively short time	100°C	2 hours
120°C	short time, followed by gradual cooling down to room temp.	120°C	30 minutes
150°C - 175°C	1 hr in ovens	175°C	2 hours

2. Articles that are used more than once

With repeated and prolonged use the migration of substances from these articles may

1. decreas
2. remain constant
3. increase

Therefore for these articles another testing scheme than that mentioned above has to be followed.
It is proposed that these articles are controlled by at least three consecutive migration tests at appropriate temperatures and times along the following lines:

1. pans and other utensils used for cooking and baking
   3 consecutive test, each lasting 2 hours at 100°C (cooking) or 150°C (baking).

2. dishes, plates, cups etc. used at temperatures up to 100°C
   3 consecutive tests, each lasting 2 hours, at 100°C.

3. bottles for soft drinks, milk, etc. used at room temperature
   3 consecutive tests, each lasting 3 days, at 40°C.

If in the course of the three consecutive tests the gross migration

- increases the relevant material must be considered to be inacceptable for repeated prolonged use
- decreases the relevant material may be accepted for the intended use if at least the gross migration in is sufficient low compared with the P.A.D.I. already in the first test
- remains constant, the relevant material is acceptable if the migration is sufficiently low as compared with the P.A.D.I.

b. Volatile Components

Volatile Components are not quantitatively measured in the gross migration test, so that the results of gross migration tests have to be corrected if volatile components are present in the material tested.
The presence of volatile components is indicated by the composition analysis.
The amount of migrating volatiles for which the results of the gross migration tests have to be corrected follows from the tests on their specific migration.

c. Shape, size etc. of the objects to be tested

Films should be tested in a "Maturi-cell", while "containers" like bottles, cups and tins should be tested as such whereby they should be filled up to 1 cm below the brim.
In case of film results should be expressed in mg/5dm^2: in case of "containers" in mg/volume used, whereafter it may converted

into mg/l in order to facilitate comparison of the test results with the P.A.D.I.

Films consisting of laminates should be tested at one side only, either by sealing sachets from the material or in a Naturi cell. Other films ("homogeneous films") may be tested at two sides, if more convenient. The total surface area may then have to be taken into account.

C. Specific migration

Specific migration tests have to be made for volatile components only in order to obtain data to correct the results of gross migration tests.
Furthermore they have to be made for those components for which the P.A.D.I. lies below the "observed gross migration" (i.e. is smaller than the amount of material migrated as determined during the gross migration tests).
Specific migration tests should be carried out using the food simulants and under the test conditions mentioned above for gross migration tests.

Final Remarks

1. Gross Migration limit

   Though it is advisable to apply the same gross migration limit as much as possible for all packaging materials and utensils, exceptions may have to be made.

2. If the actual conditions of use of a packaging material or article differ widely from the standard-test-conditions mentioned, the test conditions may have to be varied accordingly.

3. In borderline cases - as far as the results of control tests under standard conditions are concerned - it may be advisble to carry out additional control tests under actual condition of use.

29 February 1972

2. Polystyrene mixed and copolymers

2.1. description:

the products obtained by the polymerisation of styrene together with one or more of the monomers mentioned below, or by mixing polystyrene with polymers or copolymers of the monomers mentioned below. The only monomers that may be used are:

- acrylonitrile
- acrylic acid and its methyl, ethyl, butyl and octyl esters
- butadiene
- divinylbenzene, para
- ethylene
- isobutene
- isoprene
- methacrylic acid and its methyl, ethyl and butyl esters
- α-methylstyrene
- styrene
- vinylacetate
- vinylpropionate

The total content of styrene and/or α-methylstyrene used to obtain the end-product must be more than 50% on total monomers.

2.2. specification:

2.2.1. the additives added to polystyrene must be of good technical quality. No additives or substances other than those listed in this schedule may be present in the end-product.

~~N.B. The stated weight percentage additive~~, calculated on the end-product should be considered as a suggested maximum quantity. This quantity has, in a few analysed samples, not given raise to surpassing of the maximum allowable ~~quantity, indicated under 2.3~~.

a. initiators:

ammoniumperoxodisulphate
azobiscyclohexanecarbonitrile

2,2'-azobisisobutyronitrile
bis(4-tert.butylcyclohexyl)peroxydicarbonate
1,3-bis(tert.butylperoxyisopropyl)benzene
1,3-bis(α-hydroperoxyisopropyl)benzene
1,4-bis(α-hydroperoxyisopropyl)benzene
bis(3,5,5-trimethylhexanoyl)peroxide
tert. butylhydroperoxide
tert. butylperoxyacetate
tert. butylperoxybenzoate
tert. butylperoxybutyrate
tert. butylperoxydiethylacetate
tert. butylperoxy-2-ethylhexanoate
tert. butylperoxyisobutyrate
tert. butylperoxyisopropylcarbonate
tert. butylperoxypivalate
tert. butylperoxypropionate
tert. butylperoxy-3,5,5-trimethylhexanoate
cumylhydroperoxide
diacetylperoxide
diacylperoxide C_8-C_{14}
dibenzoylperoxide
di-tert. butylperoxide
2,2-di-tert.butylperoxybutane
1,1-di-tert.butylperoxycyclohexane
2,2-di-tert.butylperoxyhexane
1,1-di-tert.butylperoxy-3,3,5-trimethylcyclohexa
dicumylperoxide
diisopropylperoxydicarbonate
dipropionylperoxide
p-(α-hydroperoxyisopropyl)cumene
potassiumperoxodisulphate
p-menthanehydroperoxide

b. <u>emulsifying agents</u>:
alkyl (C_8-C_{18}) benzenesulphonate, sodium salt
alkyl (C_8-C_{18}) sulphate, sodium salt
alkyl (C_8-C_{18}) sulphonate, sodium salt
poly(etheneoxide)(=polyethyleneglycol),

molecular weight > 200, containing max. 0.3% of ethanediol and/or bis(2-hydroxyethyl) ether

poly(etheneoxide) (8-14), esterified with lauric-, oleic-, ricinoleic- and/or stearic acid

c. emulsion stabilizers:

barium sulphate
bentonite
carboxymethylcellulose, sodium salt
ethylhydroxyethylcellulose
gelatine
hydroxyethylcellulose
methylcellulose
polyvinylalcohol (viscosity of 4% solution in water at 20° C at least 20 cP)
polyvinylpyrrolidon (viscosity of 5% solution in water at 20° C at least 34 cP)
vinylpyrrolidon-polyetheneoxide copolymer, molecular weight > 1000

d. blowing agents:

adipic acid
alkanes and cyclo-alkanes, boiling point 0-100°
azodicarbonamide
succinic acid
carbonates of ammonium, potassium and sodium
citric acid
glutaric acid
levulinic acid
lactic acid
tartaric acid

e. lubricants:

bis(2-ethylhexyl)phthalate
di-n-octylphthalate
N,N'-dipalmitoylethylenediamine and/or N,N'-distearoylethylenediamine
epoxidised soya-oil with an oxiran content between 6.4 and 8%
morpholine

organopolysiloxanes, containing two methyl-groups on every siliciumatom (silicones)
paraffin, microcrystalline, of which the absorption of UV light shall meet the requirements as described in Chapter X (Methods of Investigation)
paraffin, solid, including synthetic, of which the absorption of UV light shall meet the requirements as described in Chapter X (Methods of Investigation)
paraffin, liquid (refined mineral oil), which meets the following specification:
colour less than Standard Saybolt 30
odour absent
the absorption of UV light shall meet the requirements as described in Chapter X (Methods of Investigation)
polyethylene, molecular weight $\rangle$ 200
ricinolamid
fatty acids, straight chain, saturated and unsaturated, with even number of carbon atoms C_8-C_{22}, with a maximum content of 1% of unsaponifiable matter
fatty acids, as described above, esterified with alcohols, monovalent, primary, straight chain, saturated, C_4-C_{18}, and oleylalcohol
fatty acids, as described above, esterified with glycerol to mono-, di- and triglycerides
fatty acids, as described above, salts with aluminium, ammonium, calcium, potassium, magnesium and sodium
fatty acids, as described above, salts with morpholine
zinc stearate

f. <u>antioxidants</u>:
antioxidants as prescribed in schedule 31

butylated, styrenated cresols, produced by reacting equal moles of isobutylene, styrene and a metacresol, paracresol mixture. The mixture of cresols has a distillation range of 3° C, which includes 202° C. The final product contains 20-24% of butylated cresols, 23.5-28.5% of styrenated cresols, 42-48% of butylated, styrenated cresols, and meets the following specifications: acidity not more than 0.03%, and refractive index at 25° C of 1.5500-1.5600, as determined by ASTM, D1218-61. Allowed up to a maximum of 0.5% and exclusively in polystyrene homopolymer and copolymers, and polyolefins, provided the foods and beverages do not come into contact with the packaging containing this anti-oxidant at a temperature exceeding 65° C.

g. antistatics:
bis(2-hydroxyethyl)-2-hydroxy-3-dodecoxypropyl-methylammoniumchloride
N,N,N',N'-tetrakis(2-hydroxypropyl)diaminoethane
fatty acids, as described above, as combinations with bis(2-hydroxyethyl)amine

h. UV-absorbers and -stabilizers:
2,5-bis(5'-tert.butylbenzoxazolyl-2')thiophene
2(2'-hydroxy-5'-methylphenyl)benztriazole
2-hydroxy-4-n-octoxy benzophenone

i. colorants and pigments, as prescribed in schedule 30

j. glues, inks and solvents, provided the end-product meets sect. 2, sub. c, e and f of the Packaging and Food-utensils Regulation (Food Law)

k. other substances:
calciumcarbonate, chalk
chloride of calcium, potassium and sodium
colophonium (gum, wood or tall rosins),

whether or not modified by catalytic disproportioning and entirely, partly or non-saponified to potassium- or sodiumsoaps. The product after catalytic disproportioning must contain max. 0.15% substituted phenantrene (as retene)
dibutylphthalate, blend with sucrose acetate isobutyrate
dodecylmercaptane
ethylenediaminetetraacetic acid, sodium salt
phosphates of calcium and sodium
glycerol
sodium acetate
sodium sulphate
octadecanol
1,2-propanediol
sucrose acetate isobutyrate
zinc-2-ethylhexanoate
zincoxide
zincsulphate

2.2.2. decomposition products of substances other than those listed in 2.2.1. must not be present.

2.3. <u>specification of the end-product</u> (packaging material respectively food-utensils):

2.3.1. the infrared spectrum must contain the peaks which are characteristic for polystyrene

2.3.2. the amount of volatile matter of the end-product must not exceed 0.5%

2.3.3. total gross migration of constituents of the end-product in the packaged food or beverage (determined with food simulants according Chapter X) must not exceed 12 mg per dm^2 or 60 mg per 1 food simulant

2.3.4. specific migration of the below mentioned constituents of the end-product in food simulants must not exceed the mentioned quantities (in mg per 5 dm^2 surface or in mg per 1 food simulant)

mercaptanes: not detectable	
peroxides: not detectable	
acrylamid and methacrylamid	1
acrylonitrile and methacrylonitrile	0,3
alkyl(C_8-C_{18})benzenesulphonates alkyl(C_8-C_{18})sulphates alkyl(C_8-C_{18})sulphonates	30
bis(2-hydroxyethyl)-2-hydroxy-3-dodecoxypropyl-methylammoniumchloride	2
phthalic acid diesters of fatty alcohols	40
2-(2'-hydroxy-5'-methylphenyl)-benztriazole	10
butylated, styrenated cresols	6
ricinolamid	*
1,1,3-tris(2-methyl-4-hydroxy)-5-tert.-butylfenyl)butane	3
fatty acid compositions of (2-hydroxyethyl) amine	30
zinc-2-ethylhexanoate	10

The quantity of migrating components must be determined using the methods published in Chapter X (Methods of Investigation)

* the allowable maximum migration is not yet known; unless data, leading to the establishment of the maximum permissible migration are made available before 1.1.1975, the additives cannot be permitted any more after that date.

Projet

comme annexe au projet de l'arrêté Emballages et objets usuels (Loi sur l'alimentation)

Chapitre V: Le Verre et la Céramique à base de verre

1. description

un materiau anorganique, obtenu en fondant du sable de quartz avec principalement des composés de métaux alcalins et de métaux alcalino-terreux avec ou sans oxydes d'autres éléments;
le produit non cristallin peut être du verre mais aussi du cristal, le produit entièrement ou partiellement cristallisé est de la céramique à base de verre.

1.1. types

verre d'emballage: destiné comme emballage des denrées alimentaires ou des boissons pour une ou plusieurs fois;

verre de table: aussi nommé verre de service ou verre de ménage: objets d'usage courant destinés à un emploi répété;

cristal: objets d'usage courant (par exemple des verres et des carafes) destinés à un emploi répété;

verre résistant au feu: objets d'usage courant, destinés à entrer en contact avec des denrées alimentaires ou des boissons à des températures élevées et qui sont destinés à l'usage répété;

céramique à base de verre: objets d'usage courant destinés à l'usage répété.

2. specification

2.1. le verre qui peut entrer en contact avec des denrées alimentaires ou des boissons, peut contenir des constituants, qui sont dérivés des combinaisons suivantes:

oxyde d'aluminium	oxyde de cuivre
oxyde (III) d'antimoine	oxyde de lithium
oxyde (III) d'arsène	oxyde de magnésium
oxyde de baryum	oxyde (II) de manganèse
oxyde de bore	oxyde de sodium
oxyde de calcium	oxyde de nickel
oxyde de cadmium	oxyde de rubidium
oxyde (IV) de cérium	oxyde de silicium
oxyde (III) de chrome	oxyde (IV) d'étain
oxyde (III) de cobalt	oxyde de titane
pentoxyde de phosphore	oxyde (III) de fer
fluor	oxyde de zinc
oxyde de potassium	oxyde de zirconium
	tri oxyde de soufre

2.2. Pour arriver à certaines qualités d'autres adjuvants sont permis à une concentration maximum de 0.25% (à l'exception des combinaisons de mercure).

2.3. Pour la préparation de cristal l'usage de l'oxyde (II) de plomb est permis.

2.4. Pour les noms des différentes catégories de cristal et les prescriptions concernant leur composition il faut se référer aux Directives du Conseil des Communautés Européennes du 15.12.1969 (Publication des Communautés Européennes No. L 326/36 du 29.12.1969).

3. <u>traitement</u>

le verre peut subir un traitement de surface externe afin d'améliorer la solidité.

3.1. pour un traitement à des températures élevées (jusqu'à la température d'incandescence): l'usage des combinaisons d'étain ou de titane plus ou moins volatiles qui réagissent avec la surface du verre est permis.

3.2. pour un traitement jusqu'à quelques centaines °C: les produits sont seringués avec une solution ou une émulsion aqueuse de

sel de potassium d'acide oléique
polyoxyethylène (= polyéthylène glycol), poids moleculaire > 200
le stéarate de polyoxyéthylène (8 - 14)
polypropylène

4. migration de constituants

4.1. La migration globale des constituants du produit final dans les simulants d'alimentation ne doit pas être plus élevée que l'équivalent de 12 mg par dm^2 ou 60 mg par ½ litre simulant

4.2. La migration spécifique des substances suivantes du produit final dans les simulants d'alimentation ne doit pas être supérieure à l'équivalent des quantités nommées ci-dessous (mg par 5 dm^2 ou mg par ½ litre simulant):

antimoine	0.05	fluor	1.5
arsène	0.05	cuivre	1.0
baryum	0.1	mercure	absent
bore	1.5*	plomb	0.05
cadmium	absent	manganèse	0.1
cobalt	0.05	sélénium	0.01
chrome	0.05	zinc	5.0

5. méthodes de détermination de la migration

Les conditions décrites ci-dessous ont pour but de donner une indication de la migration, dans un usage normal, des constituants du verre dans des denrées alimentaires ou boissons avec lesquels ils vont entrer en contact.

* en attendant de nouvelles données, quantité fixée provisoirement.

5.1. pour les objets qui peuvent entrer en contact avec des denrées alimentaires et des boissons à des températures moindres de 70 °C:

a. verre d'emballage:
les déterminations de migration sont faites avec de l'eau distillée ou 3% d'acide acétique à une température de 70° ± 1° C pendant une heure;

b. verre de table:
les déterminations de migration sont faites avec de l'eau distillée à 70° ± 1° C pendant une heure;

c. cristal:
les déterminations de migration sont faites avec 40% d'éthanol dans de l'eau à 40° ± 1° C pendant une heure.

5.2. pour le verre, qui peut entrer en contact avec des denrées alimentaires ou des boissons à des températures qui peuvent être plus élevées que 70° C:

a. verre d'emballage:
les déterminations de migration sont faites avec de l'eau distillée ou 3% d'acide acétique dans une autoclave dont la température est tenue à 120° ± 1° C pendant une heure;

b. verre de table:
idem;

c. verre résistant au feu et céramique à base de verre:
idem.

La quantité des constituants migrants doit être déterminée à l'aide des méthodes publiés au Chapitre X (Méthodes de Recherche).

N.B. à être discuté lors du Colloque de Rome: les conditions pour la détermination de la migration, p.e. les pots destinés pour contenir de la confiture, doivent-ils être analysés pendant 10 jours à 40° C pour déterminer la migration éventuelle?

ANNEX C

SCHEME FOR CONTROLL