

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 Rome Tel.: 39.06.57051 Telex: 625825-625853 FAO I E-mail Codex@fao.org Facsimile:39.06.5705.4593

**Agenda Item 15 B**

**CX/FAC 02/19**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

#### Thirty-fourth Session

Rotterdam, The Netherlands, 11-15 March 2002

### DRAFT MAXIMUM LEVEL FOR PATULIN IN APPLE JUICE AND APPLE JUICE INGREDIENTS IN OTHER BEVERAGES

The following comments have been received from Argentina, USA, South Africa, Poland, Denmark, IFU, ISDC

#### **ARGENTINA**

English version of the Argentine comments will be sent out as soon as possible.

#### **USA**

The 32<sup>nd</sup> CCFAC forwarded the draft maximum level (ML) of 50 µg/kg for patulin in apple juice and apple juice ingredients in other beverages to the Codex Alimentarius Commission (CAC) for adoption at Step 8. However, because consensus could not be reached, the 24<sup>th</sup> Session of the CAC returned the draft maximum level to Step 6 for further consideration by CCFAC.

The U.S. continues to support a maximum level (ML) of 50 µg/kg for patulin in apple juice and apple juice ingredients in other beverages. The U.S. imports approximately 50 percent of the apple juice it uses and welcomes a standard that reduces excessive patulin levels in apple juice and apple juice containing products. The U.S. Food and Drug Administration (FDA) also recently established an action level for patulin of 50 µg/kg on a single-strength basis in apple juice, apple juice concentrates, and apple juice products in U.S. commerce<sup>1</sup>. This level was supported by the FDA Food Advisory Committee, a committee of experts from outside the FDA that advises the agency on scientific and regulatory matters.

In support of the U.S. action level, the FDA has performed a safety assessment for patulin in apple juice<sup>2</sup>. The Provisional Tolerable Daily Intake (PTDI) for patulin identified by the FDA is the same as the Provisional Maximum Tolerated Daily Intake (PMTDI) assigned by JECFA, or 0.43 µg/kg/bw/d<sup>3</sup>. FDA's PTDI and JECFA's PMTDI include a safety factor of 100 and are based on a

<sup>1</sup> U.S. FDA, October 22, 2001, [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg510-150.htm](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg510-150.htm)

<sup>2</sup> U.S. FDA, September 2001, <http://www.cfsan.fda.gov/~dms/patubck2.html>.

<sup>3</sup> Joint FAO/WHO Expert Committee on Food Additives, 1995.

long-term feeding study in which adverse effects were observed after about 30% of the test animals' lifetime. The relevant time interval for assessing exposure is therefore long-term exposure and the appropriate intake evaluation is over a substantial portion of a lifetime.

The U.S. safety assessment calculated exposure from patulin levels in 2647 apple juice samples.

The assessment predicted that the estimated exposure for the 90<sup>th</sup> percentile of consumption would be fourfold less than the PTDI for apple juice consumers of all ages and one half the PTDI for children less than one year, assuming that the 50 µg/kg action level was in place (Table 1). For children from one-two years of age, the assessment predicted that the estimated exposure for the 90<sup>th</sup> percentile of consumption was slightly above the PTDI (0.67 versus 0.43 µg/kg bw per day), but it was 64-fold less than the no observed adverse effects level on which the PTDI was based.

The U.S. would like to reiterate that the PTDI is based on a long-term feeding study and the relevant time intervals for comparison are therefore long-term exposure and intake over a substantial portion of a lifetime. If long-term exposure to patulin is significantly below the PTDI, as it is in this case, it is not necessary for patulin exposure for every age group to be below the PTDI.

The U.S. would like to make the following additional points in support of an ML of 50 µg/kg:

- To assure compliance with an ML of 50 µg/kg, manufacturers will have to target their quality control program to a lower level, e.g., 40 µg/kg. As a result, juice will effectively be held to a standard of less than 50 µg/kg.
- Implementation of good manufacturing practices (GMPs) to assure compliance with the patulin standard will likely result in a general decline in patulin levels in apple juice. In the United Kingdom, where a patulin advisory level of 50 µg/kg was established in 1993, overall patulin levels in apple juice have declined. Prior to implementation of the advisory level, 27 percent of apple juice samples in the U.K. had less than 10 µg/kg patulin and seven percent contained 10-24 µg/kg. By comparison, of the 300 samples analyzed in 1998, 69 percent had less than 10 µg/kg patulin and 22 percent contained 10-24 µg/kg<sup>4</sup>.

As noted above, the FDA also recently established an action level for patulin of 50 µg/kg. With the action level in place, new data will be available from the U.S. in the next two years on how the distribution of patulin in apple juice will change when a maximum level of 50 µg/kg is imposed.

- Industry can meet the 50 µg/kg level with reliability, whereas the feasibility of an ML below 50 µg/kg has not been demonstrated. Even with the use of GMPs, a significant percentage of patulin levels may exceed 25 µg/kg. For example, in the U.K., despite the decline in patulin levels since the adoption of the 50 µg/kg advisory level in 1993, nine percent of the 1998 samples contained 25 µg/kg or more patulin. Also, Sydenham et al. (1995) found the patulin level in nonprocessed fruit to be 920 µg/kg<sup>5</sup>. The level dropped to 190 µg/kg following an initial water treatment step, and to 55 µg/kg following removal

by hand of rotten and damaged fruit. Further, while the most frequent patulin contamination results from surface mold, certain varieties of apples with an open calyx (blossom end) are particularly susceptible to patulin formation within the core of the apple where it is not easily observed and removed from production<sup>6</sup>. The fact that there is a significant

---

<sup>4</sup> MAFF, April 1999.

<sup>5</sup> Sydenham EW, et al., 1995.

<sup>6</sup> CX/FAC 98/17, para. 2., and The British Soft Drinks Association, November 1993.

uncertainty surrounding the ability of apple juice manufacturers to comply with a limit of 25 µg/kg makes it difficult to determine the negative impact on international trade if such a limit was adopted at this point<sup>7</sup>. What is needed is the development of more information on the feasibility of implementing 25 µg/kg.

- A Codex Code of Practice for the Prevention of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (CX/FAC 01/23) is currently being drafted by CCFAC. This code will help further control patulin levels.

At the 24<sup>th</sup> Session of the CAC, the Belgian Delegation, speaking on behalf of the European Community, noted that recent exposure assessments indicated that although the lifetime exposure to patulin is below the PTMDI, the exposure of children to patulin through the consumption of apple juice was in the range of, or even exceeded, the PMTDI for a considerable portion during childhood. Because of this concern, the European Commission initiated a study to evaluate the dietary intake of patulin. The Belgian Delegation noted that the results of the study were expected to become available in the beginning of 2002 and therefore recommended that the CAC delay adoption of the draft ML for patulin<sup>8</sup>. As explained above, the U.S. believes that a standard of 50 µg/kg is adequate to protect the health of the entire population. The U.S. believes that an ML for patulin should be adopted in a timely manner in the interest of setting limits for a contaminant that can be a serious health concern.

## **SOUTH AFRICA**

South Africa is of the opinion that lowering the level of patulin below 50 µg/kg is unnecessary as there is already a double safety factor built into the threshold level. Lowering of the threshold value would be impractical from a processing point of view. At the rates the fruit are processed in some bigger plants, it will be nearly impossible to remove fruit properly in order to attain a lower level. Many of the processors, particularly in developing countries, cannot afford the labour to do the sorting. It is also important to note that patulin can be present in seemingly good fruit.

## **POLAND**

Poland sustains previously submitted maximum level for patulin in apple juice and apple products: 30 • g/kg, which is in compliance with our national regulations.

## **ISDC (INTERNATIONAL SOFT DRINK COUNCIL)**

The International Soft Drink Council (ISDC) is a non-government organization representing the worldwide soft drink industry. ISDC is pleased to submit comments at Step 6 on the draft maximum level for patulin in apple juice and apple juice ingredients in other beverages.

We support the adoption of the draft maximum level of 50 µg/kg for patulin in apple juice and apple juice ingredients in other beverages. The proposed maximum level of 50 µg/kg is within the analytical capability of the methodology. At levels below 50 µg/kg, the detection of patulin by current methodology is not reliable. Enforcement of a lower limit would be difficult.

The U.S. Food and Drug Administration (FDA) has recently concluded that the 50 µg/kg maximum level is adequate to protect the public health, particularly infants and children who consume large amounts of

---

<sup>7</sup> CX/FAC 99/16.

<sup>8</sup> ALINORM 01/41, paras. 116-118.

apple juice. Exposure estimates conducted in the United Kingdom support this conclusion. They show that even the youngest age group consuming directly produced apple juice would not exceed the PMTDI set by JECFA based on the mean level of patulin (Food Standards Agency 2001). The concentration of patulin in apple juice made from concentrates is consistently lower than in fresh apple juice. Therefore, there is no demonstrable benefit to be gained by reducing the limit below 50 µg/kg in apple juice.

## DENMARK

In CL 2001/42-FAC governments have been invited to comment at step 6 on the draft maximum level of 50 µg/kg for patulin in apple juice and apple juice ingredients in other beverages.

Patulin is a toxic substance with suspected carcinogenic properties. A provisional maximum tolerable daily intake (PMTDI) for patulin of 0.4 µg/kg bw has been established by JECFA in 1995.

As argued by Denmark at previous CCFAC meetings Denmark find, that a limit of 50 µg/kg of patulin in apple juice is too high as it does not sufficiently protect children who drink apple juice. Children can easily exceed TDI if apple juice contains 50 µg/kg of patulin.

Calculations made by USA based on the assumptions that children drink 200 ml apple juice pr day and based on the distribution curves on patulin content in apple juice shows that children in the age of 0-2 easily exceeds TDI. This calculation does not take other sources of apple juice into consideration.

Danish investigations on content of patulin in apple juice has given the following result:

Product	No of samples	Range	average	Median	Year
Apple juice	46	< dl – 27 µg/l	5.1 µg/l	4,1 µg/l	1985
Applejuice	57	<dl –18 µg/l	4.9 µg/l	-	1994

These data shows that it is possible to produce apple juice with a content below 25 µg/kg and that this limit only rarely will be exceeded. Therefore, Denmark supports a limit of 25 µg/kg and cannot support a limit of 50 µg/kg.

The degree of patulin contamination correlates with the degree of spoilage. Therefore, a code of practice is of great importance in order to reduce the contamination of patulin, as trimming away the spoilt portion of the fruit, patulin contamination can be reduced by up to 90 %.

## IFU (INTERNATIONAL FEDERATION OF FRUIT JUICE PRODUCERS)

Our Federation regretted very much that it was not possible to find a consensus at the 24<sup>th</sup> Session of the Codex Commission in order to ratify the maximum level of 50 µg Patulin per kg of apple juice. According to our understanding all facts for the fixation of this limit were given.

We do not intend to repeat once more all arguments in favour of the 50 µg/kg as this has been done already several times during the procedure up to step 8. We would just like to stress three main arguments, which according to us, were not taken into consideration sufficiently during the last Sessions of the CCFAC and the Session of the CAC:

- 1. Consumption:** we are waiting for the study of the EU which was announced at the 24<sup>th</sup> Session of the CAC. According to a study of *CRÉDOC, Enquête INCA 1999*, children at the age of 3 – 6 years had an average consumption of 52 ml / day, of which 62 % were drinking apple juice only once a week, 19 % twice a week and 9 % three times a week. These figures are far below of those presented before.
- 2. Calculation of the daily intake of Patulin:** It is absolutely not justified to take the limit of 50 µg as basis for the calculation. Most juices have a content of Patulin which is far lower than 50 µg/kg. Juices with a content of 50 µg are without any doubt the exception and the average even in countries

with a higher risk of elevated Patulin contamination (mainly countries with warm climate) have an average value which is 30 – 40 % below the limit.

**3. Attitude of the fruit juice industry towards this problem:** The members of our Federation are doing everything possible to keep the Patulin content as low as possible. The success of fruit juices on the market is highly related to its image as a natural and healthy product. We therefore support the establishment of the Code of Practise for the Prevention of Contamination of Apple Juice by Patulin. The imputation brought forward by certain self nominated “experts” that the fruit juice industry is interested in a high limit for Patulin because they want to process rotten fruit is unfair and proves lack of knowledge of the fruit juice industry. The fact is that Patulin also occurs in fruit which is absolutely sound from the outside so that it is not possible to remove such fruit during sorting.

According to this statement our Federation is in favour of maintaining the

**Maximum Limit for Patulin at 50 µg/kg.**