Sudan Red and Related Dyes – White Paper

What is Sudan?
The red dyes Sudan I, II, III and IV are oil soluble, azo dyes used legally in the leather and fabric industries. They are fairly inexpensive and readily available. However, they are not approved at any level for use in foods. The International Agency for Research on Cancer (IARC), a part of the World Health Organization, has assessed the Sudan dyes as Group 3 genotoxic carcinogens. The Group 3 category is used most commonly for agents, mixtures and exposure circumstances for which the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

Statements issued by the Food Standards Agency (FSA) in the United Kingdom have indicated that the risk is very small from consuming items contaminated with the dyes. However, their use in food products is illegal.

The industrial dye Para Red is chemically similar to Sudan I and is also an industrial dye not permitted for use in food. Other dyes under scrutiny are Sudan Orange G, Sudan Red 7B, and Butter Yellow.

Background
In May of 2003, the European Authority reported finding Sudan I in ground capsicums produced in India. Levels of 4,000 ppm Sudan I were identified in products from two Mumbai (formerly Bombay) based shippers.

In response to the adulteration, the European Union issued Decision 2003/460/EC requiring as a condition of import that all hot chilli and hot chilli products be tested for Sudan I. The Decision was amended in January of 2004 (2004/92/EC) to include Sudan II, III and IV. This requirement remains in effect.

The Indian Spices Board suspended the Certificates of Registration for the two shippers identified in the 2003 cases. Several exporters have also had their registrations revoked for violation of the conditions of registration relating to food safety. The Spices Board implemented a mandatory sampling and testing program for Sudan I in all chilli and chilli products (excluding oils and oleoresins) exported from India effective October 23, 2003 irrespective of their final destination. The program was expanded to include the other Sudan dyes (II through IV), and in September 2004, the certification became an integral part of the customs clearance process.

In 2004, the dyes were detected in unrefined palm oils and a series of EU Rapid Alerts were issued.

In February 2005, the FSA issued a notice that Sudan I was detected in Worcester sauce produced in the United Kingdom and food products containing the sauce were recalled. The source of the dye was traced to contaminated chilli used as an ingredient in the sauce which arrived in the U.K. in 2002, prior to the implementation of the control measures.
The normal aging process for Worcester sauce was a factor contributing to the incident. The recall of the sauce and other products in which it was used is the largest in history.

Other recalls soon followed. In March, products containing Sudan were recalled in China, Canada and South Africa.

On April 2, 2005 two products in the U.K. were recalled because the seasoning mix reportedly was contaminated with the chemical dye Para Red. Para Red is chemically similar to Sudan I and is not a permitted color in the U.K.

In April 2005, the EU imposed emergency measures adding turmeric and palm oil to the list of foodstuffs requiring written certificates stipulating that they have been tested and are free of the Sudan dyes.

In May 2005 the number of products recalled due to reported contamination from Para Red rose to almost 70. The UK Seasoning and Spice Association sent a letter to the FSA offering its fullest possible cooperation with authorities in looking at the presence of non-permitted dyes in food.

At the same time, the EU announced the limit of detection for dyes Sudan I and other similar dyes is in the range of 0.5 and 1.0 milligrams per kilogram (0.5 – 1.0 ppm) using the HPLC method. For the time being any food containing dyes above those limits must be withdrawn from the market. However, joint efforts are underway among scientists in four countries, including the UK and Spain, to further develop the analytical method for Para Red, to extend it to similar dyes and to improve the consistency of the results. The limit of detection is in effect until work is completed on the methods. A review of toxicological data on Para Red and other similar dyes has also been ordered.

The U.S. Food and Drug Administration (FDA) is monitoring the situation, but has not issued any formal guidance to industry. Unofficially, FDA officials have said that although not legal for food use in this country, the levels they have seen of these materials in food in the U.S. are not high enough to justify aggressive enforcement at this time. Should the situation change, FDA retains full authority to act against food containing these colors.

**Why was it done?**
Adulteration is done for a variety of reasons and in the case of Sudan, it appears the dye was added to improve the color of the capsicum products.

The color of a capsicum involves two separate functionalities, extractable and visual. The extractable color is principally related to paprika and visual/surface color applies to all capsicums.

Studies conducted by ASTA member laboratories and the Indian Spices Board show that Sudan I would need to be present at levels of 120 ppm or more to raise the extractable
color one ASTA Color unit using ASTA Method 20.1. Since this makes no economic sense it is assumed that this was done to affect the visual (surface) color. Reports have indicated that levels of several hundred to 1,000 ppm of Sudan I are required to impact the visual appearance.

**How was it done?**
The production of ground chilli is typically a two-step process. The dried pods are cut into small pieces and then ground to the required final mesh size. Investigations indicate that the adulteration is likely to occur between the first and second milling.

The process involves preparation of a concentrated Sudan oil solution, which is then added to a small quantity of rice flour or chilli. This mixture is then blended into the product during the final milling. The concentrated material would likely contain several percent of the dye. For example, preparation of a 5% chilli coated product (50,000 ppm) would then be blended into a 10 metric ton lot resulting in a level of 250 ppm Sudan Red in the final product.

There have been reports that farmers could be using the concentrated oil solutions to coat the whole pods, however, preliminary research indicates this is not likely given the waxy nature of the capsicum pods. The waxy surface is thought to prevent the absorption of the color.

A series of tests have been conducted in the Research and Development facility of an ASTA member to validate this hypothesis. Samples of fresh and dried pods were soaked and sprayed with oil solutions containing various levels of Sudan dyes. In all instances the amount of Sudan needed to impact the visual color of either the pod or the stem was at least 1,000 ppm. The most significant factor however, was that all pods exhibited an atypical shine and the color was easily transferred to paper or the technicians’ hands. The presence of the dye on wholes pods would therefore be readily detected as part of any incoming raw materials inspections program.

**Detection**
If capsicums are being purchased as whole pods, a solid knowledge of the product and a strong inspection program of incoming materials should capture any intentional adulteration of the whole pods as the adulteration is apparent upon visual inspection.

Analytical testing may be required as part of the raw material program if one is procuring ground goods unless the supplier can assure positive control back to the agricultural source.

Since 2003 a number of methods have been put forward utilizing High Performance Liquid Chromatography (HPLC). The mode of detection, UV, PDA (Photo Diode Array) or HPLC/MS will directly impact the limits of detection. The actual sample matrix will impact the detection limits as well.
Utilizing standard UV, a limit of quantification (LOQ) of 1 ppm is easily achieved. There are various carotenoids which are present in capsicums also absorb in the range of the dyes, especially Sudan III, and at low levels can result in false positives.

The UK developed a method for the detection of Sudan I – IV. The result of collaborative work for Sudan I is available on the FSA Website.

The ASTA Technical Committee reviewed a number of methods and based on performance in several laboratories published a method which committee members believe incorporates the best features of each. The method, ASTA 28.0, is an HPLC with UV detection at 505 nm. HPLC-MS is being used for detection and quantification at the ppb level. The ASTA Method is also believed to be effective for determining the presence of Para Red, Sudan Orange G, Sudan Red 7B, and Butter Yellow dyes in capsicum samples.

Microscopic examination of ground material will also assist in the detection of dyes and other adulterants. The presence of filler such as rice and atypical spice particulates are easily recognized. ASTA has developed a CD-ROM which identifies a number of them as well as what the “pure” material would look like.

**Prevention**

A number of steps need to be taken to prevent spice adulterated with Sudan from entering the food supply.

First, companies need to be very familiar with their vendors. Ensure that your vendors have control of their raw materials and adhere to Good Manufacturing Principles as the principle means of prevention. Require certification as warranted.

If spice is found to be adulterated with Sudan, take aggressive action, including legal steps. All of the suspect product should be destroyed to prevent it from being blended down or used in smaller portions in the hopes of avoiding detection. Failure to destroy the product and remove it from the supply chain will only result in further contamination. All receivers of raw ground Capsicums from countries other than the U.S should sample and test this product for the presence of illegal color additives. The ASTA sampling procedure along with ASTA Method 28.0 should allow for use of the spice with confidence.

Establishing solid inspection and surveillance programs is key to maintaining the integrity of the total supply chain.

**Implications**

The cost of the Sudan adulteration has been very high, both for the companies involved and for others in the industry. It’s estimated that in the EU alone, the Sudan problems have cost hundreds of millions of dollars. The cost of recalling food products is tremendous. Honest suppliers from India who were providing product free of Sudan have lost business as buyers sourced from other markets. Many other companies have faced
the additional financial burden of testing. The entire industry has suffered as a result of the actions of a few.

**ASTA Activities**

ASTA’s primary role is to keep members informed about issues such as Sudan. ASTA relies on its monthly electronic newsletter FYI ASTA, email bulletins and the ASTA Web site to provide critical information to members.

The Technical Group has reviewed a method for the determination of the Sudan and other dyes and has made it available for all members through the Web site. An ASTA CD-ROM, “Microscopic Identification of Spices” was developed to assist with identification of pure spice and common adulterants. A technical forum was held in January 2005 featuring information on all aspects of adulteration, with further information provided at the 2005 Annual Meeting in Phoenix. The ASTA Self-Regulation Program was unveiled in October 2004 and members who believe they have received adulterated spice are encouraged to file a complaint through that program.

**References**

**ASTA**

ASTA Method 28.0 – Available free to ASTA Members at the ASTA Web site: http://astaspice.org/members/technical/method28intro.cfm

ASTA CD-ROM, “Microscopic Identification of Spices – Members can purchase for $100 by visiting the ASTA Web site: http://astaspice.org/members/Resources/publications.cfm

ASTA Self-Regulation Program – Details can be found on the ASTA Web site at: http://astaspice.org/members/regulatory/selfprogram.cfm

Non-Members should contact the ASTA office at info@astaspice.org for details on purchasing ASTA products.

**European Union**


**Indian Spices Board**

Alerts - http://www.indianspices.com/

**FSA**


**IARC Monographs** - http://monographs.iarc.fr/