PURE OAT PRODUCTION

The outline below starts with a summary description of the methods used by Cream Hill Estates (CHE), at this point in time, to produce pure oats that are free of cross-contamination. This is followed by a more detailed explanation for readers who may be interested in the exact processes and the rationale behind them. Traceability is extremely important to the success of this venture. As we move along in the process we are looking at other monitoring measures that we can put in place to ensure meeting or improve on the standards.

Background:
Gluten contamination in oats usually comes from the presence of wheat, barley, rye and other cereal grains that are closely related to wheat (WBR). These cereal grains appear in oats because of contamination:

- in oat seed at planting time
- of fields during growth
- of equipment used for harvest, transfer, transport, storage and processing.

We have developed a process that ensures our oats are free of contaminant cereal grains.

Seed Purity:
This process starts with a specific quality of seed that is entirely free of contamination.

Field Purity:
Seed is planted in fields that have not grown any WBR cereal crops for at least the previous three years. Seed growers (specialized farmers) are familiar with and apply methods that are standard within the seed-growing industry to ensure purity. In addition we look for farmers who have a vested interest in ensuring purity because they have a family member who has celiac disease.

During growth, the fields are kept clear of contaminating cereal grains by separating them from fields that are growing WBR, so that no contaminant grains are being grown within 30 feet from the edge of the WBR-free field.

Equipment Cleanliness:
Harvest, transfer, transport, storage and processing of the oats into food products is done by dedicated and/or thoroughly cleaned equipment to ensure all of our products are contamination-free.

Purity Verification:
Non-contamination levels are verified in three stages to ensure purity:

1. While the crop is still standing in select-seed-growers' fields, the Canadian Food Inspection Agency (CFIA) routinely inspects the field in which the crop is growing and issues a report – either a "seed crop inspection" report for purity of plant variety and presence of contaminating crop and/or weed plants or a "land use" report for presence of

contaminating crop and/or weed plants only. Thus, we would expect that a plot that meets "select" standards would have a maximum of 1-3 variant crop plants per 10 acres, and some of these might be non-offending plants such as corn, bean, pea, etc. This is standard CFIA practice and we are looking at ways to improve this verification process.

2. After the seed is harvested samples are taken from each wagon or truck for testing. The samples are sent to a federally certified seed laboratory where the seeds are examined one-by-one and weed and other crop seeds are removed and counted. Thus, we know exactly how many WBR seeds are present in a given sample, and this sample quite accurately represents the amount of contamination in the whole wagon/truck.

3. After processing into flakes or flour 1-tonne bulk bags are sampled, and the samples are sent to another federally certified lab for R5-ELISA testing. Each bulk bag is sealed after sampling to ensure integrity. Any bag testing more than 20 ppm (parts per million of gluten) is sold to another company to be used as regular commercial oats.

Detailed Summary:
This detailed summary is intended to take the reader through the steps that Cream Hill Estates (CHE) takes to produce "pure oats" that are intended for use by people who follow a gluten-free diet. It is based on an actual sequence of events that is followed in producing different purities of seed according to long-established practice at Agriculture and Agri-Foods Canada (AAFC), the Canadian Seed Growers Association (CSGA) and the Canadian Food Inspection Agency (CFIA).

Seed Designations:
CSGA has established a specific nomenclature for seed purity such that "Breeder" is the purest, followed by "Select", "Foundation 1", "Foundation 2", "Registered 1 & 2" and "Certified". The next, and least pure, food type is "Commercial" – which, in the case of oats, is what horses eat. The earliest steps in seed production are not presented here, nor are definitions of purity below "Foundation 1", as they are not relevant to current issues.

Foundation 1: "Foundation 1" identifies a seed purity in which no more than 1 variant crop seed is present in 1 kg of preferred seed. "Foundation 1" does not address the issue of genetic purity, so that if there are plants of the preferred variety that are taller or shorter or of slightly different colour growing among the preferred plants, these variant plants are not removed. "Foundation" seed is normally not grown on an AAFC farm, rather on a commercial seed farm. "Foundation" seed can be grown on very large plots of land – hundreds of acres if necessary – and is subject to the same general CFIA inspections that apply to all seed. However, here the inspector cannot practically walk and evaluate a whole, say, 200 acre field, so he/she picks a number of representative small segments of the field and inspects those. CFIA has a standardized procedure that inspectors follow in deciding how to inspect for "Foundation", "Registered" and "Certified" designation. During "Foundation 1" inspection, the inspector removes variant crop plants from the area under inspection, and may walk over to remove plants in an area outside that being inspected if it is nearby.

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Seed Purity:
Cream Hill Estates uses oat seed for food production that improves on the cross-contamination purity standards of "Foundation 1" seed. For our purposes this equates to less than 1 WBR seed per 1 kg of oats. In seed numbers this would be less than one variant crop seed per about 25,000 oat seeds.

Field Purity:
Our seed is planted on land that has not had any WBR growing on it during the 3 previous years. (Seed growers routinely keep records of what crop variety has been grown on any particular field for the previous 3-5 years.) An isolation strip of 30 feet is maintained around the perimeter of each field. During oat growth, the isolation strip is kept free of WBR by either tilling or mowing, depending upon what kind of strip it is – cultivated, sod, etc – so that WBR plants do not grow there and thus are not carried into our oats by wind, etc.

At "heading out", CFIA inspectors do a "land use inspection" on each field and report the number and varieties of variant crop plants they find and remove them, following which they complete a CFIA land use report that records their findings. The select-seed-grower also walks the oat field looking for variant crop plants and removes them.

Equipment Cleanliness:
Every piece of equipment used in producing our pure oats is either dedicated to our processes or thoroughly cleaned before use to ensure that there is no source of cross-contamination by WBR. For the combine, this means partially disassembling it and blowing out with high pressure/high volume air all places where seed of any kind can become lodged. A high-capacity industrial vacuum cleaner is used, as vacuum sometimes dislodges particles that air pressure doesn't disturb. This includes the internal threshing mechanism, the storage bin and the augur, which are the only parts on the machine with which the oats come into contact. The truck or wagon into which the augur discharges is thoroughly cleaned the same way. The augur that carries oats from the truck/wagon to a storage bin, and that bin too, are similarly cleaned before use. When oats are taken from the farm to the processor all transfer, transport and storage equipment is similarly cleaned. Once bins are cleaned, they are dedicated to storage of our oats. Similarly, the processing machinery at the mill is completely cleaned and they process only soy and oats, no other contaminant cereal grains. Equipment at the packaging plant is dedicated to our "pure oats".

Storage Sampling and Testing:
After combining and transport to the farmstead, seed is stored in one or more, as necessary, 5,000 bushel (150 tonne) storage bins until the processor is ready to receive it for cleaning and manufacturing into flakes or flour. While in storage, the seed is sampled for testing using a 6' – 8' Seedboro bin probe. Once inserted to the desired depth, the inside pipe is rotated so it's holes match the locations of holes in the outside pipe. Thus, seed from all depths falls into the inside pipe. The inside pipe is then rotated again to close the holes, and withdrawn. Seed is dumped from the probe through the open handle end into a bucket. After a number of such bin samplings have been completed, each sample is then packaged into a separate Ziploc bag, labelled and the bags are sent to a federally certified seed laboratory for testing.

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Transport to Processing Plant:
Bulk seed is augured into a cleaned truck and transported to the processor, where it is again stored in a clean 150 tonne bulk bin. If smaller quantities are to be processed, the seed is augured into new 1-tonne bulk bags (which by definition are clean), and transported to the plant.

Processing Plant Cleaning:
The processing plant cleans the seed, removing stalks, kernels with hulls still attached, dirt, stones, metal, weed and other contaminating seeds, etc. This cleaning machinery, the stabilizing line and the flaking mill are cleaned with high pressure/volume air and industrial vacuum cleaners to ensure that no residual contaminants remain. The mill is used only for oats and soy, so the likelihood of contamination before cleaning is already low. Samples are taken of the oat groats and the flaked oats and are sent to the federally certified lab for testing. If R5-ELISA testing is above the allowable amount of gluten in ppm, oats from this bag are not used for consumption by people with celiac disease.

Final Testing:
Oat flakes and whole kernels (groats) are packed into 1-tonne bulk bags or 25 pound/kg bags for shipment to Cream Hill Estates in Montreal. The 25 pound bags are sampled at the mill as they are being packaged. Upon receipt in Montreal, each bulk bag is bin-probed to obtain a sample for R5-ELISA testing. The bags are then sealed with numbered plastic seals to ensure and maintain bag integrity. Upon acceptable R5- ELISA test results being received by Cream Hill Estates, the bulk bag contents are packaged in a CFIA-approved "clean room" and the 25 pound bags are available for shipping. No WBR-containing products are permitted in our facility, so we are able to maintain WRB contamination-free conditions.

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