

November, 2020.



MONTANA
FOOD & CONSUMER
SAFETY PROGRAM



Articles This Month

1. Training Updates and Opportunities
2. Cracking Covid-19
 - o Gym & Fitness Center COVID Compliance
3. Licensing Update
4. The Food, Dietary Supplement & Drug Continuum
5. What's next? Exploding Candy?
6. Daycares: What is 'Safe Siting'?
7. Featured Interview: Paige Tolleson
8. Fun Facts: Crossword Puzzle



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ORIGINAL ART BY JOHN FALTER

1. TRAINING OPPORTUNITIES



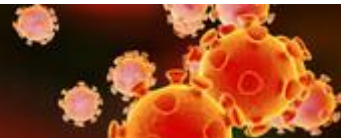
Upcoming Webinar

"Review of UV and Ionization Disinfection Solutions": **Tuesday Dec. 1 at 9 a.m.**, by Bernie Erikson, Executive Vice President, FSG ([Facility Solution Group](#))

Join us for a webinar on the use of UV lights and other technology for disinfection in public buildings. Mr. Erikson recently presented at the Montana High School Administrators conference. His company supplies facilities with lighting and electrical options. This presentation will review UV and Needle Point Bi Polar Ionization solutions for disinfection of both surfaces and air. The presenter will cover practical deployments and relative third-party validation, using specific examples for various applications for public facilities, such as restaurants, hotels, and schools.

-Nina

2. Cracking Covid-19



Gym and Fitness Center COVID Compliance

Under the Governor's directive released May 19, 2020, gyms are allowed to operate at 75 percent capacity. This capacity was not reduced with the latest directive, which targeted bars, restaurants, and public gatherings.

Masks are required to be worn in gyms, per the [mask directive](#). There is an exemption for "persons engaged in an activity that makes wearing a face covering impractical or unsafe, such as strenuous physical exercise or swimming" (page 4). This does not mean that gym members can remove their mask once they are inside the gym. Masks must still be worn in the workout area when traveling between equipment, resting, or performing any activity that is not strenuous. Mask must also be worn when in locker rooms and other areas in the gym.

Additional rules and restrictions for gyms can be found in the [Governor's directive](#) appendix B page 1.

-Staci

3. LICENSING UPDATE



Renewals are in full swing!

Important updates:

1. Gail will be out until December 7th
 - Please direct licensing questions to Keturah Fortner in her absence
2. Upcoming licensee notification
 - The post card reminder will be mailed out the week of December 14th
 - The next email reminder will go out December 4th
3. Change of ownership notifications
 - We have received a number of responses to our emails and mailings stating a change of ownership has occurred. These notifications are being forwarded to you for confirmation.
4. Email 'Undeliverable'
 - Approximately 8000 emails were sent out and 2000 were returned as 'undeliverable'. We will be removing the undeliverable email addresses from the database. This may impact the PHEP deliverable asking you to update contact information in the database.

-Ed

4. The Food, Dietary Supplement, & Drug Regulation Continuum

Each product is governed by a distinct set of rules

There is a regulation continuum between food, dietary supplements and drugs. The regulations are designed to produce safe products and have taken more than 100 years to painstakingly develop.

The least complex set of regulations is for providing safe food. The most stringent set of regulations applies to drugs. And dietary supplements lies in the middle of those to regulation sets (see illustration).

FOOD, DIETARY SUPPLEMENT, & DRUG REGULATION CONTINUUM



Depending primarily on product ingredients and labeling claims, each product has a chance of becoming the other. However, each product is regulated by a different set of safety rules. Sometimes the hard part for the regulator is determining what regulations apply in a given circumstance and that requires knowledge, training and education.

For example, gummy bears: the chewy sweet treat most children love. It's small, cheap, cute and colorful!

Gummy bears are basically comprised of lots of sugar, gelatin and water, heated for a few minutes to reconfigure the ingredients into the food phenomenon it has become. However, add in a little [cannabidiol](#) (CBD) to the recipe and now you have—not a simple gummy bear candy loved by children—but an unapproved drug, manufactured primarily for adults that includes a [Schedule V](#) controlled substance. It's that easy. Throw in a few wild [health claims](#) about how CBD can fight [COVID-19](#) and you'll soon have an outrageously noncompliant and unapproved drug.

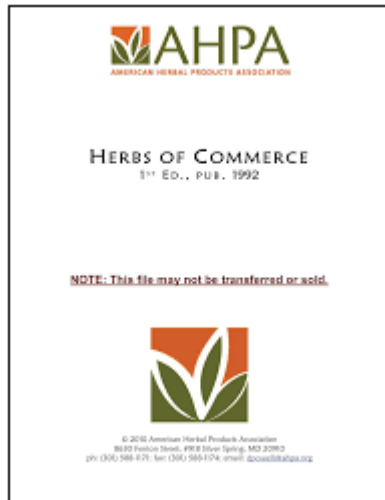


Food, dietary supplements and drugs must all have packaging labels—either as [bulk commodities](#) or [consumer commodities](#). They also have ingredients: maybe one, but most times a lot more than one in any processed food.

For foods, the simplest ingredient is to have just one component, like raw honey or an unprocessed whole fruit or vegetable. In this situation, package labeling for raw honey or for a bag of whole cherries is so simple, no ingredients list is required, only the product's common name, net weight and business responsible for the product. [All ingredients](#) in foods must recognized as being either: 1) a conventional food used commonly in the United States prior to 1958 like raw honey or unprocessed cherry fruit, 2) [generally recognized as safe](#), 3) as an [approved additive](#) listed in code, or, 4) [properly petitioned](#) for use in accordance with federal Food and Drug Administration procedures.

The key difference between food and a dietary supplement is dietary supplements are also allowed to have an additional component in products, known as "[New Dietary Ingredients](#)," or "NDIs" in sanitarian parlance. In other words, like food, dietary supplements must meet the same minimum labeling and safety standards, but they are allowed go a step beyond food. This because they can have ingredients and components that were not marketed in the United States before October 15, 1994. The major problem with this allowance is there

is [no definitive list](#) of dietary ingredients that were marketed in supplements before that date. This means manufacturers and distributors are ultimately responsible for determining if an ingredient is a "new dietary ingredient." And that fact adds a burden on regulators to know about ingredients to properly aid novice and ambitious food entrepreneurs in steering them down the road to compliance.



However, help is available.

There is a chance that if an arcane or esoteric plant or plant part is listed in the 1992 "[Herbs of Commerce](#)" book, the final product is probably regulated as a dietary supplement. However, please consult with the Food and Consumer Safety Section, before rendering a regulatory opinion on usage of unusual plants and plant parts. Proper use of this book beyond common food naming convention often gets very tricky.

The important tradeoff is if the ingredient cannot meet criteria 1-4 listed in the previous paragraph of this article, the ingredient must meet NDI criteria and be tested for purity, strength and composition for the active ingredient or component in the final product. Also, dietary supplements that do meet criteria 1-4, but process a biologic into an active ingredient to render them a supplement rather than food, the final product must also undergo purity, strength and composition testing. This can be accomplished in one of two ways, but both ultimately rely on laboratory analysis of the final product to establish active ingredient limits that determine adulteration boundaries ([21 CFR 111.70](#)). If a product contains an ingredient that exceeds the boundary, the product is adulterated and compliance measures must be enacted to reestablish control, which can range from market recalls to reprocessing the product.

For a specific ingredient, let's look at another example from the elderberry plant (*Sambucus sp.*). Elderberry plant, like other products during the pandemic, has been heavily marketed on many websites as a treatment to COVID-19. Therefore, our agency has addressed an increasing number of Montana merchants who want to sell [elderberry products](#) as cottage foods and conventional foods.

The juice itself is safe to drink, if obtained from ripened fruit that has [Brix value](#) at least [11.0](#) (percent by weight of sugar solids in a pure sucrose solution). And elder flowers are also safe, if used within the limits to be considered a spice, seasoning or flavoring ([21 CFR 182.10](#)). However, complications arise if using other parts of the plant and underripe elderberries. Specifically, unripe elderberries and other parts of the tree, such as the leaves and stems, contain toxins like [sambunigrin](#), and have the potential to create low levels of cyanide that can cause [adverse health consequences](#), ranging from nausea to vomiting

and diarrhea. While technically, the elderberry plant does not contain cyanide toxin, it does have *cyanogenic glycosides*, which are carbohydrate derivatives that can produce cyanide, if ingested.

In summary, sanitarians should be aware of suspicious ingredients in edible products and unsupported health benefit claims that are associated with a product. We try to address these issues during the pre-licensing review process, but they sometimes emerge after the business has been issued a license. Therefore, be wary when conducting routine inspections.

For further information on this topic, feel free to visit the [wholesale food webpage](#), or contact me.

-Jeff



5. Cottage Food: What's next? Exploding candy?

Recently we have received a few proposals for a new cottage food—freeze dried candy. The operator takes candy and places in a home freeze dryer, such as the Harvest Right home freeze dryer. They run a freeze dry cycle—chewy candy such as Skittles will expand and become crunchy. This process removes water from the candy to differing degrees, depending on the type of candy used. Freeze drying involves freezing the product, lowering pressure, then removing the ice by sublimation (remember your chemistry--going from solid to vapor without passing through the liquid phase). Further heating may be carried out to remove additional water. Little water remains in the product after freeze drying.



This process may be approved for cottage food under the following conditions: the operator must start with commercially available candy that is not TCS—Skittles and taffy are some of the more popular candies used. Candy must be handled with gloves to avoid bare hand contact before and after freeze drying. The operator must not package the item with oxygen absorption packs or in vacuum packs. These activities would require additional review.

-Nina

6. Daycares: What is 'Safe Siting'?

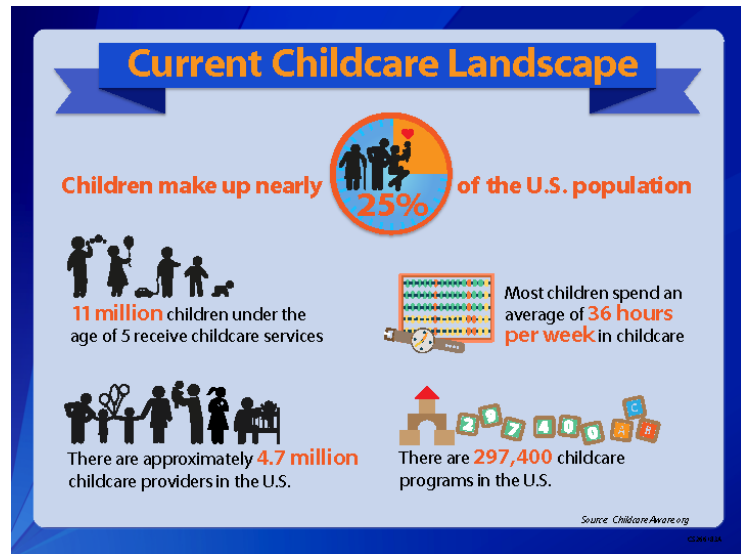
Montana's Choose Safe Places for Early Care and Education Program - Guest column from our partners at the Office of Epidemiology and Scientific Support

DID YOU KNOW? In Montana, more than 39,000 children are served by over 900 childcare facilities for an average of 36 hours per week.

The Montana Environmental Health Education and Assessment (MEHEA) team is excited to re-launch our Montana Choose Safe Places for Early Care and Education (CSPECE) initiative, funded by a cooperative agreement grant between Montana Department of Public Health and Human Services (DPHHS) and the Center for Disease Control and Prevention (CDC). Our goal is to ensure that early care and education programs are located in safe places – called safe siting - so that children aren't exposed to dangerous chemicals during their care. We want to help professionals in public health, community planning, licensing, environmental protection, early care and education, and other fields work together to create safe siting practices in their communities.

What is safe siting?

Safe siting is the process in which daycare and childcare center properties are screened for potential environmental hazards related to naturally occurring substances (e.g., arsenic or radon) or historic and current industrial and/or agricultural activities (e.g., Superfund sites). Our team uses various tools to evaluate whether children are exposed to hazardous chemicals in drinking water, soil, and air.



Key Safe Siting Considerations for Inspectors:

- Have harmful chemicals ever been used, made, or dumped at the site?
- Are businesses using harmful chemicals near the site?
- Is the site at risk for naturally occurring contaminants like radon?
- Is the drinking water safe?

How does MEHEA's CSPECE program work?

Participation in our CSPECE program is voluntary. MEHEA is working hard to engage stakeholders, partners, and providers to ensure that every center is safely sited. We are especially focused on **new** centers because we can engage them early on during the licensing process. To do this, we have a safe siting checklist for providers/inspectors, and we will soon go live with an online Safe Siting Assessment survey that can be submitted directly to us for review. We will review all available data sources and provide a written consultation to the current or prospective providers.

We hope you will share this information with providers you work with and help us make every site in Montana 100% safe! Visit our regularly updated [website](#) for additional details and tools to assist you with site inspections.

We would love to hear from you if you have feedback or suggestions for improving the effectiveness of our CSPECE Program. You can email Environmental Health Program Specialist, Scarlett Fuller, at scarlett.fuller@mt.gov.



Choose Safe Places
for Early Care and Education
Planning. Guidance. Protection.

7. Featured Interview: Paige Tolleson



This article highlights Paige Tolleson, who is graduating this month from MSU Bozeman's accredited environmental health degree program and is pursuing an environmental health career in Montana.

Interview of Paige Tolleson by advisor, Dr. Mari Eggers

Mari: Paige, in addition to the extensive coursework you have completed for your accredited environmental health degree, what have been your experiences in applying this knowledge?

Paige: Over the past four years at Montana State University I have had wonderful opportunities to conduct research in the field of Environmental Health. The first research project I worked on was in 2018, researching *E.coli* and coliform contamination in Bozeman and Matthew Bird Creeks. I worked in the field collecting water samples as well as in the lab running the samples. In continuation of this project I interned at the Environmental Health Department [of the Gallatin City County Health Department] working for Lori Christenson on researching the age distribution and permit status of septic systems within the study area. We wanted to see if there was a correlation between failing systems and *E. coli*/coliform contamination.

After finishing these projects, I gained further interest in water quality work and found myself working as Mari Eggers' teaching assistant on a project addressing arsenic

contamination in home well water in Three Forks, Montana. She, her environmental health students and I worked with Three Forks' science students and their teachers to implement a free well testing service. Our goals were to assess and increase local awareness of the health risks posed by arsenic and *E. coli* in private drinking water sources. One of my tasks on this project was to use GPS to create a GIS map of the

neighborhoods in the School District, in order to visualize groundwater arsenic distribution. Currently, I'm writing up a progress report on this project, for Three Forks High School and the community, as they will continue this work after the pandemic.

Mari: What resources have been available to you to be able to do this work?

Paige: In my three and a half years at Montana State I applied for and was awarded funding from Montana IDEA of Biomedical Research Excellence (INBRE) for these two consecutive research projects, a stipend from the Rocky Mountain Student Leaders in Public Health training center, and the William G. and Mary H. Walter Scholarship for excelling in the Environmental Health Program in 2020. I also was selected to present my research on arsenic contamination at the National Environmental Health Association's 2020 Annual Education Conference, and at the National Council of Undergraduate Research's national conference.



Mari: What do you like to do in your free time?

Paige: Well I came to Montana for the skiing and all of the access to various outdoor activities. With that being said, I really love rock climbing, trail running, backpacking, and of course skiing. I definitely work hard in order to play hard!

Mari: What are you hoping to do after graduating this month?

Paige: I am extremely grateful for all of the research and community engagement opportunities that MSU has provided and would love to pursue a career in Environmental Health. I am interested in many aspects of Environmental Health and would be interested in working in a public health department, research lab, hospital or in industry. My interest for pursuing a career in environmental health stems from my research experiences. I have really enjoyed the interpersonal communication with communities as well as coworkers coupled with the raw research to address an important health hazard. I am very excited to begin my career in Environmental Health, and appreciate the amazing education I have gotten from Montana State University. If you know of an opportunity anywhere in Montana, I would appreciate hearing from you!

Paige Tolleson can be reached at paige.tolleson5@gmail.com. Resume and references available upon request.

8. FUN FACTS



ALL PART OF THE JOB.
Can you complete the puzzle below?

F N V T T O E L H X K U B D Z
M O E A C U U T I L K O K R W
J H O T E L P T Y S D D E A Z
N M R D F B O P B Y N G O Z W
L S L C N C O I A R A E I A X
T A K P I M L R X W E F T H W
V N Z I S V T X E T A A Z U J
B I A H I D I S B Q U D K I E
A T K R D C O N S U M E R G L
M I U U U K M H D H F G A B E
Z Z A V Y A Q J B Q R R C L X
T E P Z S K T R B O E U X H N
H T E W N K G S V V K P J Q X
T N E M T R A P E D T H R G K
E S N E C I L B Q R E M T S V

WORD BANK

- BEVERAGE
- BODYART
- CONSUMER
- DEPARTMENT
- DISINFECT
- FOOD
- HAZARD
- HOTEL
- LICENSE
- OUTBREAK
- POOL
- RESTAURANT
- SANITIZE
- SEWAGE
- UTENSIL

Created by [Puzzlemaker](#) at [DiscoveryEducation.com](#)

Click here for
answers to last week's puzzle
and a printable version of our
fun fact!

Contact Information

FCS Staff Listing

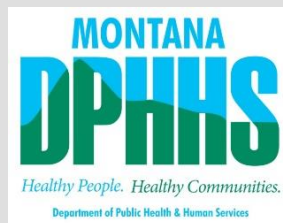
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If you are in crisis and want help, call the Montana Suicide Prevention Lifeline, 24/7, at 1-800-273-TALK (1-800-273-8255) or text 'MT' to 741-741.

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