TECHNICAL REPORT: OREGON HEALTH AUTHORITY'S PROCESS TO DETERMINE WHICH TYPES OF CONTAMINANTS TO TEST FOR IN CANNABIS PRODUCTS, AND LEVELS FOR ACTION

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Technical Report: Oregon Health Authority's Process to Determine Which Types of Contaminants to Test for in Cannabis Products, and Levels for Action*

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BACKGROUND

This report describes the process the Oregon Health Authority (OHA) followed to establish the list of contaminants for cannabis testing. It also describes how OHA established an action level for each of these contaminants.

These lists and action levels have now been implemented in Oregon Administrative Rules (OAR 333-7-0010 through 333-7-0100 and OAR 333-7-0400 and 333-7-0410 Exhibit A).

This report documents the rationale and justifications for:

- The selection of target contaminants for testing; and
- Testing regimes for cannabis and cannabis-derived products.

The three major categories of contaminants targeted for testing include:

- Microbiological contaminants;
- Pesticides; and
- Solvents.

OHA is committed to evidence-based decision making when drafting and implementing OARs. As research into cannabis use and safety advances, the OARs related to cannabis testing and this report will be revised and updated to reflect the state of the science.

Not all types of cannabis products need testing for all three of these contaminant categories. Below is information on each of the three major categories of contaminants targeted for testing.

In developing the OARs and this document, OHA relied on the expertise of individuals from various organizations named in the "Acknowledgments" section. Their expertise ranged from pesticide use in Oregon, pesticide regulation in Oregon, analytical chemistry, laboratory accreditation, microbiology, cannabis processing and cannabis cultivation. They also represented a range of organizations including the Oregon Department of Agriculture, commercial analytical chemistry laboratories, state laboratories and state laboratory accreditation personnel. Throughout this document, this group will be referred to as the "Technical Expert Work Group" or the "work group."

MICROBIOLOGICAL

The Technical Expert Work Group recommended that cannabis products be tested for *E. coli* and *Salmonella.* The work group also advised that products not be allowed to go to market if any *Salmonella* is detected or if *E. coli* is detected at levels higher than 100 CFU/g. In general, bacteria cannot survive either the drying or heating processes that occur when cannabis is prepared for smoking. *Salmonella,* however, can survive when very little moisture is present, and it can easily infect humans. *E. coli* does not usually pose a significant health risk; however, its presence indicates poor sanitary conditions and that other fecal bacteria may be present. Testing for both organisms in cannabis products will, therefore, protect public health.

The only other *microbial* organisms of concern on cannabis are several species of *Aspergillus* mold. *Aspergillus* can cause respiratory infections in individuals who inhale it if they are severely immune-compromised. These individuals should avoid smoking cannabis. However, OHA Administrative Rules do not require testing for *Aspergillus;* the mold is so common in the environment that a person could pick it up many different ways. A positive test result would not mean the product is unsafe for most uses for most people. Therefore, the work group recommended that cannabis products intended for smoking and other inhalation uses include a warning about this risk for people with suppressed immune systems.

Some states have required testing of cannabis for *aflatoxins* produced by certain *Aspergillus* species. Oil-rich seeds must be present to produce these toxins on plants. Commercial cannabis does not contain these seeds. As a result, the Technical Expert Work Group recommends against such testing.

Water activity

Water activity is a measure of how moist something is in units called "A_w". Most pathogenic microbial organisms cannot grow when water activity is less than A_w 0.65. Testing for water activity and requiring water activity levels to fall below A_w 0.65 will ensure the absence of microbial growth on cannabis products during storage and before sale.

PESTICIDES

Target analyte list development

Work group members established three lists of *target analytes* related to pesticides. OHA compiled the three lists and filtered it by criteria agreed upon by the work group.

- Work group members created the first list as described in Appendix 1 of a white paper titled "Pesticide Use on Cannabis" published by the Cannabis Safety Institute in June 2015.(1) This list contained 123 active ingredients.
- The work group generated the second list by identifying compounds that overlapped between various other lists. This included the first list described above; Oregon, Nevada or Colorado regulations for medical or recreational marijuana; and other lists.
- The work group generated the third list based on integrated pest management guidance for several crops grown in the Pacific Northwest. It also included a search of the Pesticide Information Center Online (PICOL) database. Additionally, work group members made a list of the active ingredients in pesticide products available at a local hardware store. Once this information was compiled, work group members compared their master list to the first two lists described above and removed any redundancies.

OHA compiled these three submitted lists and removed duplicates. This resulted in a starting list of 188 pesticide analytes.

Table 1 describes the process by which the work group scored and filtered the compiled list of 188 pesticide analytes. First, they scored active ingredients based on general (human) toxicity, analytical capacity, detection frequency in cannabis samples in Oregon and general availability. All scoring parameters were reduced to a four-point scale (from zero to three). Then, OHA added scores across the parameters to get a composite score for each pesticide active ingredient.

An OHA toxicologist initially scored active ingredients for toxicity. An Oregon State University toxicologist and an Oregon Department of Agriculture (ODA) representative with some training in toxicology reviewed and approved the toxicity scoring. Three analytical laboratories participating in the work group independently scored analytical capacity and detection frequency in Oregon's cannabis.

OHA averaged these independently submitted scores and rounded averaged analytical capacity and detection frequency scores to the nearest whole number (0.5 was rounded to 1).

ODA scored general availability based on registration status and general knowledge of use patterns. Every pesticide product must be registered for specific uses with ODA. As a result, ODA has expert knowledge on which pesticides are used for which purposes in Oregon.

Table 1. Scoring process for each target pesticide analyte on OHA's compiled list

Low (0) — Priority to keep on list — High (3)

	0	1	2	3
General toxicity	No data	*Fungicides*, plant growth regulators	Pyrethroid, neonicotinoid, pyrazole and pyrimidine, and macrocyclic lactone insecticides and *acaricides* and insect growth regulators	*Organophosphate*, organochlorinated and *carbamate* insecticides.
Analytical capability	Not tested	Expensive and/or analytically challenging to test in cannabis	Some labs said feasible, other labs said not feasible	Multi-instrument, "easy" clean-up, all labs in agreement
Detection frequency (in cannabis)	Tested but never detected	Not tested	Single detection	Multiple detections
Availability	Not available or ODA experience suggested this analyte would not be used or detected in cannabis	Restricted use pesticide registered for a single crop or use	Restricted use pesticide registered for multiple crops or uses	General use pesticide (no license or other certification needed to purchase or use products with this active ingredient); ODA knowledge that the analyte is frequently used illegally and likely to be used on cannabis

Once scoring was complete, OHA applied an extra point to the composite score for each analyte that scored 2 or higher for detection frequency in cannabis. Detection frequency indicates this pesticide active ingredient is already being used in Oregon's cannabis. As a result, OHA placed greater emphasis on detection frequency than on other parameters in cannabis. This weighting process ensured that composite scores would reflect this emphasis on pesticides known to be used in Oregon's cannabis.

Every analyte with a composite score of 8.5 or higher was retained on the final list. Analytes with composite scores below 8.5 were removed from the list. OHA selected 8.5 as the cutoff score because it was the highest score that captured all pesticide active ingredients that had ever been detected in cannabis in Oregon.

Pesticides, continued

After filtering out all analytes with a score lower than 8.5, OHA addressed work group experts' special requests.

- First, ODA and analytical laboratory representatives recommended not including any *organochlorine* insecticides on the list. For the most part, these compounds have been banned for decades. Any *organochlorine* contamination would be at low levels due to historical uses in the area from decades ago as opposed to direct, recent application to cannabis. This request removed *chlordane* from the list of target analytes.

- Second, commercial analytical laboratory representatives recommended adding etoxazole, fenpyroximate, fludioxonil, methiocarb, methomyl, MGK-264, oxamyl, propiconazole, spinosad, spiromesifen, spirotetramat, thiacloprid and trifloxystrobin to the list of target analytes. This request was based on Technical Expert Work Group members' special knowledge of cannabis grower practices and potential for use of these compounds.

- Third, with two exceptions (piperonyl butoxide and pyrethrins) OHA removed analytes from the list that will be included in ODA's list of pesticides that may be allowed for use on cannabis. This step removed azadirachtin from the target analyte list for pesticides. Piperonyl butoxide and pyrethrins may be allowed for use on cannabis. However, they remain on the target analyte list because of potential for misuse. OHA counterparts in Colorado, where some marijuana has already been tested for pesticide residues, reported to OHA that they have found very high concentrations of piperonyl butoxide (up to 50 parts per million [ppm]) in *cannabinoid* concentrates. They also report that piperonyl butoxide and pyrethrins are typically used together.

The resulting target analyte list, shown as Table 2, includes 59 target analytes along with their action levels.

Developing action levels

OHA set action levels for pesticide active ingredients based on presence/absence. Analytical chemistry laboratories can only certify the absence of an analyte down to each laboratory's limit of quantification (LOQ). Therefore, OHA set action levels based on presence/absence listed as a reasonable LOQ that accredited laboratories should be able to achieve.

Ideally, action levels would be based on human health and toxicity thresholds. However, health risk from pesticides results from a combination of:

- The inherent toxicity of the pesticide; and

- The level of exposure to the pesticide people have.

Pesticides, continued

OHA has a lot of information about the inherent toxicity of pesticide active ingredients. However, OHA does not currently have enough information about exposure levels to pesticides from the various uses of contaminated cannabis products. Therefore, OHA could not base action levels on health risk and instead set them on LOQs; OHA based the criterion for pass/fail on whether or not an analyte is detected above the action level. Cannabis samples with pesticide active ingredients detected above the action level fail and the product must be destroyed.

To set action levels, OHA asked commercial analytical laboratories to submit their LOQs for each analyte on the target list in cannabis. Two labs submitted LOQs, while a third lab submitted limits of detection on the instrument types from published literature. For each instrument type, OHA multiplied the higher of the LOQs from the two laboratories by a factor of 2 to generate the action level. There were some analytes that no labs in Oregon had experience testing in cannabis, so there were no LOQs to submit. In those cases, OHA selected the highest action level from among analytes with the same published detection limits for the relevant analytical laboratory equipment.

Piperononyl butoxide and pyrethrins are on both OHA's target analyte list and ODA's list of pesticides that may be allowed on cannabis. OHA adopted Nevada's action levels for these analytes. Nevada's action level for piperonyl butoxide is based on its state laboratory's limit of quantification for this compound in the cannabis matrix. The Nevada lab's action level of 1 ppm for pyrethrins is based on the lowest federal food tolerance for pyrethrins in edible plant material. The Washington Department of Health is also adopting Nevada's action levels for these two compounds. OHA adopted Nevada's action levels primarily to be consistent with policies in neighboring states.

Uncertainties

- Scoring system for pesticides – No scoring system is perfect. Each category of scoring has areas of uncertainty where professional judgment was applied.
    - » Toxicity scoring – The toxicity of pesticide active ingredients is highly variable within classes and dependent upon other compounds included in the final product formulation. No scoring system can perfectly condense the complexity of pesticide toxicology into a four-point ranking system. Some *fungicides* may, for instance, be more acutely toxic than some *organophosphate* pesticides. The work group did not have time or resources for an in-depth assessment of each active ingredient in all its formulations. Rather, compounds were ranked based on chemical class. This assumes that, generally, insecticides and *acaricides* are more toxic to mammals than *fungicides* and plant growth regulators. In addition, *organophosphate*, *organochlorine* and *carbamate* insecticides will generally be more toxic than other insecticide classes. OHA and OSU toxicologists agreed that this rough ranking system was adequate for the purpose of screening and prioritizing active ingredients for inclusion in the target analyte list.

Pesticides, continued

- Analytical capacity – This scoring relied heavily on the professional judgment and experience of the analytical chemists on the work group. This parameter was difficult to score because ease of analysis is highly dependent on the type of equipment used and extraction methods necessary for that instrument. Chemists on the work group tried to remain objective regarding the type of equipment used.
- Detection frequency – This was the most straightforward parameter to score. Laboratory representatives in the work group reported whether they had or had not detected or tested for each contaminant in cannabis samples.
- Availability – This parameter had less uncertainty than other scoring categories. It was generally based on registration status augmented with ODA's knowledge of which pesticides are commonly used illegally and likely used on cannabis.

- Action levels
  - Because cannabis recently became legal in three states, scant research exists on exposure to establish toxicity-based tolerances for pesticide residues in cannabis products. The variety of uses and exposure routes is too great. There is also not enough information about the *pyrolysis* products of target pesticides relevant to cannabis products when smoked.
  - Some analytes in cannabis have not been tested in cannabis by any Oregon analytical laboratory. For these analytes, OHA used *surrogate analytes* with similar published detection limits. This is not ideal, but represents the best available estimate at this time. Administrative Rules requiring that labs submit their LOQs along with sample results will allow OHA to update action levels in Administrative Rule based on data as appropriate in the future.

Table 2. Pesticide analytes and their action levels

Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1

Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins*	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins†	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

* Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

Pesticides, continued

SOLVENTS

Background

Some producers of cannabis products use solvents to extract and/or concentrate the active ingredients from cannabis. Similar processes are also used to produce other pharmaceutical products. The Oregon Health Authority (OHA) adopted a list of target solvent analytes to be applied to cannabis extracts and concentrates (Table 3). The purpose of testing for these solvents and common solvent contaminants is to ensure that these compounds, if present, do not exceed levels that would be expected to harm cannabis users' health.

Target analyte list development

A work group member representing a laboratory that does testing for residual solvents in other pharmaceuticals created the list that OHA adopted. This work group member is also familiar with common extraction and concentration techniques and solvents used in Oregon's cannabis industry.

Developing action levels

The action levels are based on the "International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Impurities: Guideline for Residual Solvents Q3C(R5)" (ICH Q3C).(2) The only solvents commonly used in the cannabis industry for which no action levels have been established are *butane, propane, 2-methylbutane, methylpropane, 2,2-dimethylbutane, 2,3-dimethylbutane, 2-methylpentane and 3-methylpentane.*

Butane, propane, 2-methylbutane and methylpropane are short-chain alkanes similar to pentane. Pentane falls into a class of solvents designated as class 3 by ICH Q3C. Class 3 solvents are less toxic and default to a health-based action level of 5,000 ppm residual. Because of the similarities to pentane, OHA assigned action levels of 5,000 ppm for butane, propane, 2-methylbutane and methylpropane.

OHA assigned *n-hexane's* action level of 290 ppm as the action level for 2,2-dimethylbutane, 2,3-dimethylbutane, 2-methylpentane and 3-methylpentane because they are *isomers* of *n-hexane*.

The health-based action levels in the ICH Q3C are based on the toxicity of the individual solvent and on the magnitude of exposure likely to occur from consuming 10 grams of the pharmaceutical. Ten grams is a health-protective assumption. It is unlikely that anyone would consume more than 10 grams of cannabis extract or concentrate in a single day.

Uncertainties

- Action levels
  - » No health-based solvent residual limits have been established specifically for cannabis extract or concentrate products. However, practices around pharmaceutical production and limits provide a reasonable model. This especially pertains to the oral consumption of cannabis products.
  - » We are uncertain whether the selected action levels for solvents in cannabis products sufficiently protect persons who smoke cannabis. However, the ICH Q3C does assume 100% absorption by any exposure route. This covers inhalation, which is how some pharmaceuticals are administered.

Table 3. List of solvents and their action levels

Solvent	Chemical Abstract Services (CAS) Registry number	Action level (µg/g)
1,2-Dimethoxyethane	110-71-4	100
1,4-Dioxane	123-91-1	380
1-Butanol	71-36-3	5000
1-Pentanol	71-41-0	5000
1-Propanol	71-23-8	5000
2-Butanol	78-92-2	5000
2-Butanone	78-93-3	5000
2-Ethoxyethanol	110-80-5	160
2-methylbutane	78-78-4	5000*
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butane	106-97-8	5000*
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
2,2-dimethylbutane	75-83-2	290†
2,3-dimethylbutane	79-29-8	290†
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
1,4-dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5000

Solvent	Chemical Abstract Services (CAS) Registry number	Action level (µg/g)
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
n-Hexane	110-54-3	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Methylpropane	75-28-5	5000*
2-Methylpentane	107-83-5	290†
3-Methylpentane	96-14-0	290†
N,N-dimethylacetamide	127-19-5	1090
N,N-dimethylfromamide	68-12-2	880
Pentane	109-66-0	5000
Propane	74-98-6	5000*
Pyridine	110-86-1	200
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes‡	1330-20-7	2170

* Limit based on similarity to pentane.

† Limit based on similarity with n-hexane.

‡ Combination of: 1,2-dimethylbenzene, 1,3-dimethylbenzene, 1,4-dimethylbenzene, and ethyl benzene.

Solvents, continued

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2. International Council for Harmonisation. European Medicines Agency. *ICH Guideline* Q3C (R5) on impurities: Guideline for residual solvents. 2015 September. Available at www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/03/WC500104258.pdf.

DEFINITIONS

Unless otherwise noted, definitions were provided by the author.

***acaricides*:**
Pesticides that kill members of the arachnid subclass acari, which includes ticks and mites.

action level:
The level of a contaminant (pesticide or solvent) that, if found in a cannabis product, triggers agency action to prohibit that cannabis product from being sold.

aflatoxins:
A group of chemically similar fungal metabolites produced by certain strains of molds in the genus *Aspergillus*. They are a subset of the larger class of fungal metabolic toxins known as mycotoxins.

analyte (from http://dictionary.reference.com/browse/analyte):
A substance or chemical component that is undergoing analysis.

Aspergillus (from "American Heritage Dictionary"):
Any of various fungi of the genus *Aspergillus*, which includes many common molds.

A_w: See "Water activity" definition.

cannabinoid:
A class of chemicals, unique to cannabis (marijuana), derived from cannabigerolic acid and known to interact with cannabinoid receptors.

carbamate:
A class of pesticides derived from carbamic acid that inhibits the acetylcholine esterase enzyme in the target species.

CFU/g:
Colony forming units per gram. Refers to a measure of the amount of living bacteria per given amount (1 gram) of a sample.

E. coli *(Escherichia coli)****:***
A species of bacteria found in large quantities in the human digestive tract. Presence of *E. Coli* can indicate fecal contamination.

fungicide:
A chemical pesticide designed to kill or prevent the growth of fungus.

isomer:
A molecule with the same chemical formula as another molecule, but with a different chemical structure.

limit of quantification (from www.ncbi.nlm.nih.gov):
The lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

microbial (from "Stedman's Medical Dictionary"):
Relating to any minute organism.

microbiological (from "Stedman's Medical Dictionary"):
Concerned with microorganisms, including fungi, protozoa, bacteria and viruses.

organochlorine (from "American Heritage Dictionary" with modifications):
Any of various hydrocarbon (containing carbon and hydrogen) pesticides, such as DDT, that contain chlorine as the dominant functional group.

***organophosphate*:**
Any of several organic chemicals that contain an *organophosphate* or organo-thiophosphate ester as the primary functional group, some of which are used as fertilizers and pesticides. For more information on ester, go to www.merriam-webster.com/dictionary/ester.

pyrolysis (from "American Heritage Dictionary"):
Decomposition or transformation of a compound caused by fire.

Salmonella:
A species of bacteria that causes illness in humans.

solvent:
A substance that can dissolve another substance, or in which another substance is dissolved, forming a solution. For example, water can be used as a solvent to dissolve salt. In chemistry, various solvents are used to extract a chemical of interest from the substance in which it is naturally found. In the case of cannabis, some processors use solvents to dissolve THC (the active ingredient in marijuana) so it can be extracted or separated from the cannabis plant.

surrogate analyte:
Surrogates are compounds similar in chemical composition to the analytes of interest and spiked into environmental samples prior to preparation and analysis. They are used to evaluate extraction efficiency and matrix interference on a sample-specific basis. In some settings a surrogate analyte that is easy to measure may be used as a substitute to estimate the concentration or presence of another analyte that is difficult to measure but often co-occurs with the surrogate.

target analyte:
A chemical the lab must test for to see if it is present in cannabis.

water activity (or A_w):
The partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water.

Definitions, continued

Technical report:

Oregon Health Authority's process to determine which types of contaminants to test for in cannabis products, and levels for action

The marijuana universal symbol means a product contains marijuana and should be kept in its original packaging, out of the reach of children.

Oregon Health Authority
PUBLIC HEALTH DIVISION

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