

Killing Me Softly: The Qualified Exempt Story in Colorado



COLORADO
Department of Agriculture

Colorado's Program Highlights



Program Staffing:

2018: 3 FTE plus 2 FTE Subaward for Ed & Outreach
(No Inspections)

2021: 2.6 FTE Plus 2 FTE Subaward for Ed and Outreach

2023: 3 FTE No Subaward (Ed and Outreach Internalized)

July 1: 2.6 FTE (1.2 Inspectors) Loss of Program Coordinator who handled Education & Outreach, Inspector Training, Registration and Farm Inventory. More changes are still coming as funding does not carry us through to June 30, 2026.

Colorado's Program Highlights



Farm Inventory:

Covered Farms*:	87		
Qualified Exempt*:	108		
Commercial and Discretionary Exempt*:	9		
Micro-Exempt:	411		
Other(RCR):	70		
TOTAL:			685

*Annual Registration Required

CO and the Rocky My Divide

Some Fun (And Not so Fun Facts):

Geographically CO is the 8th largest state covering over 104,000 square miles. (About 2 times NC or 10 MA)

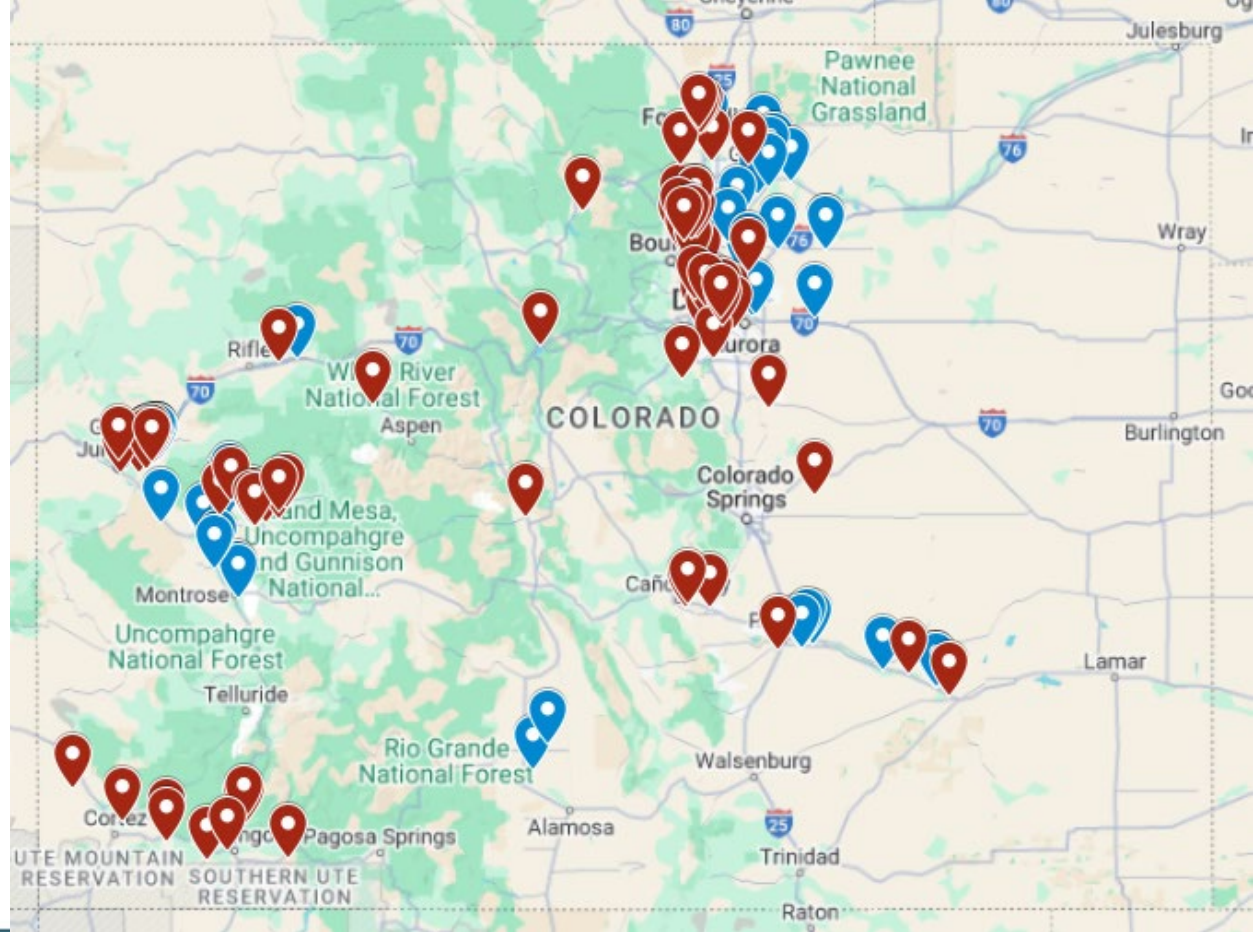
The Rocky Mountains divide the state and only 6 main highways cross the state east to west and fewer north to south.

Our inspectors work in multiple programs and live where most of the Divisions work is performed, i.e. Denver Metro.

Surprise!!! Our growers are mostly NOT in Denver!!!!



Location of All Farms Required to Register



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General Misunderstanding

Clarification and Points of Confusion:

- 1) Qualified Exempt farms believe they are **EXEMPT** from the rule so they don't register or keep records.
- 2) They don't review their sales records or won't attest that more than 50% of their sales are to qualified end users.
- 3) "I'm not that big, none of this applies to me."
- 4) Don't know who is a 'qualified end user'!!!!

Adding to the Confusion



Lack of Clarity or Guidance:

In Dec of 2021 growers pushed back on our interpretation of Qualified End User. We reached out to several states and found differing opinions. We reached out to the FDA and got differing opinions.

Submitted ENA on April 5th, 2022 to print materials to help farms understand our interpretation. Resubmitted May 10th, 2022. July 15th, 2022, still no authorization.

After meeting with CFSAN submitted 3 scenarios for review, No response. 10 additional scenarios submitted Feb 2023.

Finally July 3, 2024 the FDA SME sent an email answering the question but no Guidance for states produced to date to.

Qualified Exempt Explanation

Definition and Clarity:

To clarify “whether sales to a retail distribution warehouse qualify as a qualified end user sales” the answer is NO, because the “distribution warehouse” does not meet the definitions of “consumer”, “retail food establishment” nor “restaurant” (see definitions at 21 CFR 1.227) as part of the requirements for eligibility of the qualified exemption (§ 112.5) to the Produce Safety Rule.

- A far cry from “where was the check written” and months (years) of adding confusing statements.

Why Was That Answer Critical

Colorado Project

The FDA SME answer aligned with our interpretation. No more uncertainty about what a Qualified End User or Qualified Sale was. It set in motion a QE Project in CO.

Farms that either don't register as required annually or register but won't sign an affidavit confirming they have reviewed their records as required under § 112.7 (b) are considered a covered farm and subject to an inspection.

Why is that important?



Misunderstanding or Evasion

Farmers Talk

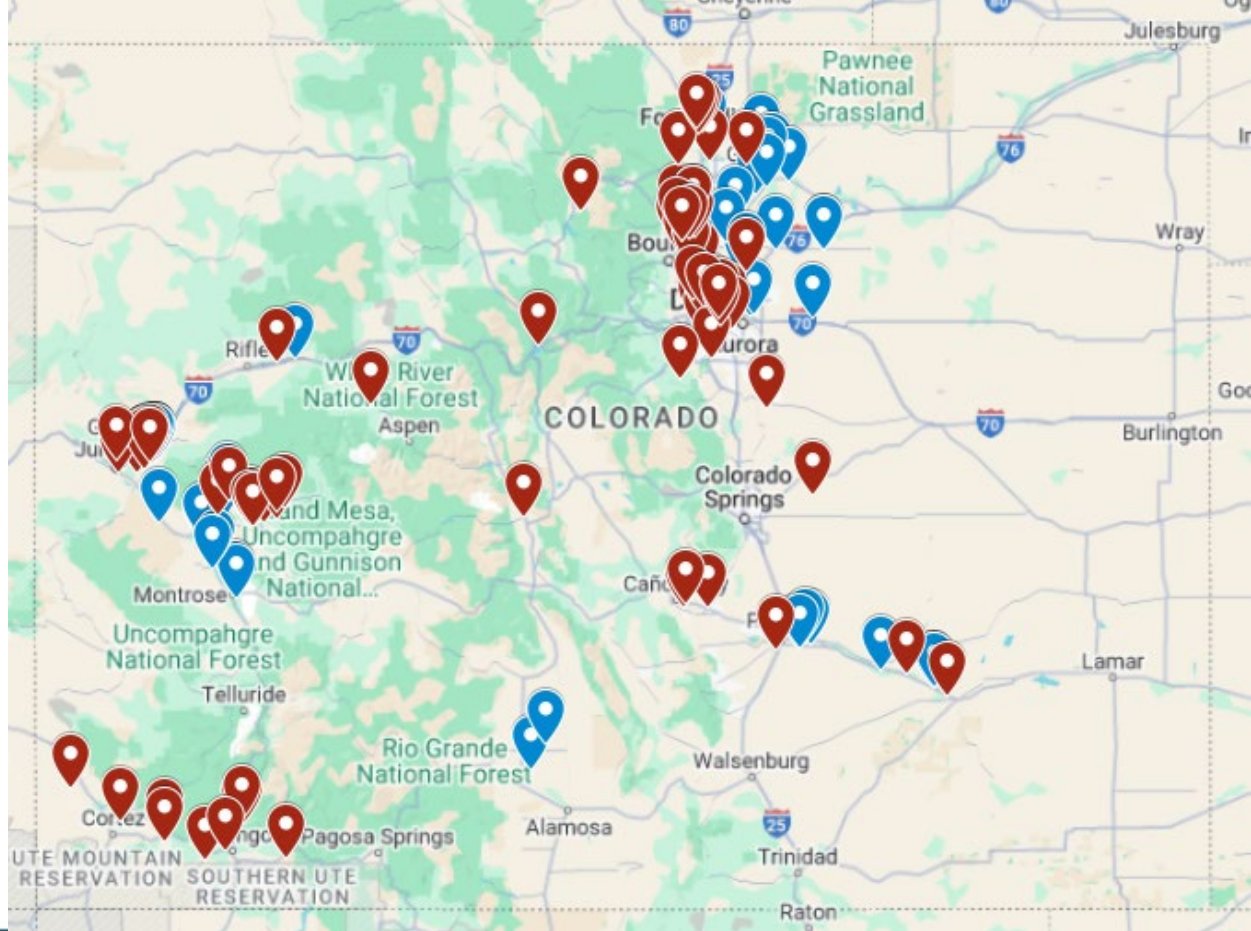
There are pockets in CO where every farmer has claimed QE status.

There are certain product groups where registration is low and a higher percent claim QE or Micro-Exempt status.

We suspect some QE farms are shipping out of state beyond 275 miles or partnering with neighbors to fill orders and claiming that produce as part of their sales percent for QE status but not their sales volume. (Keeping sales low and % QE high)

Remember This Map?

Blue are Covered
Red are Qualified Exempt



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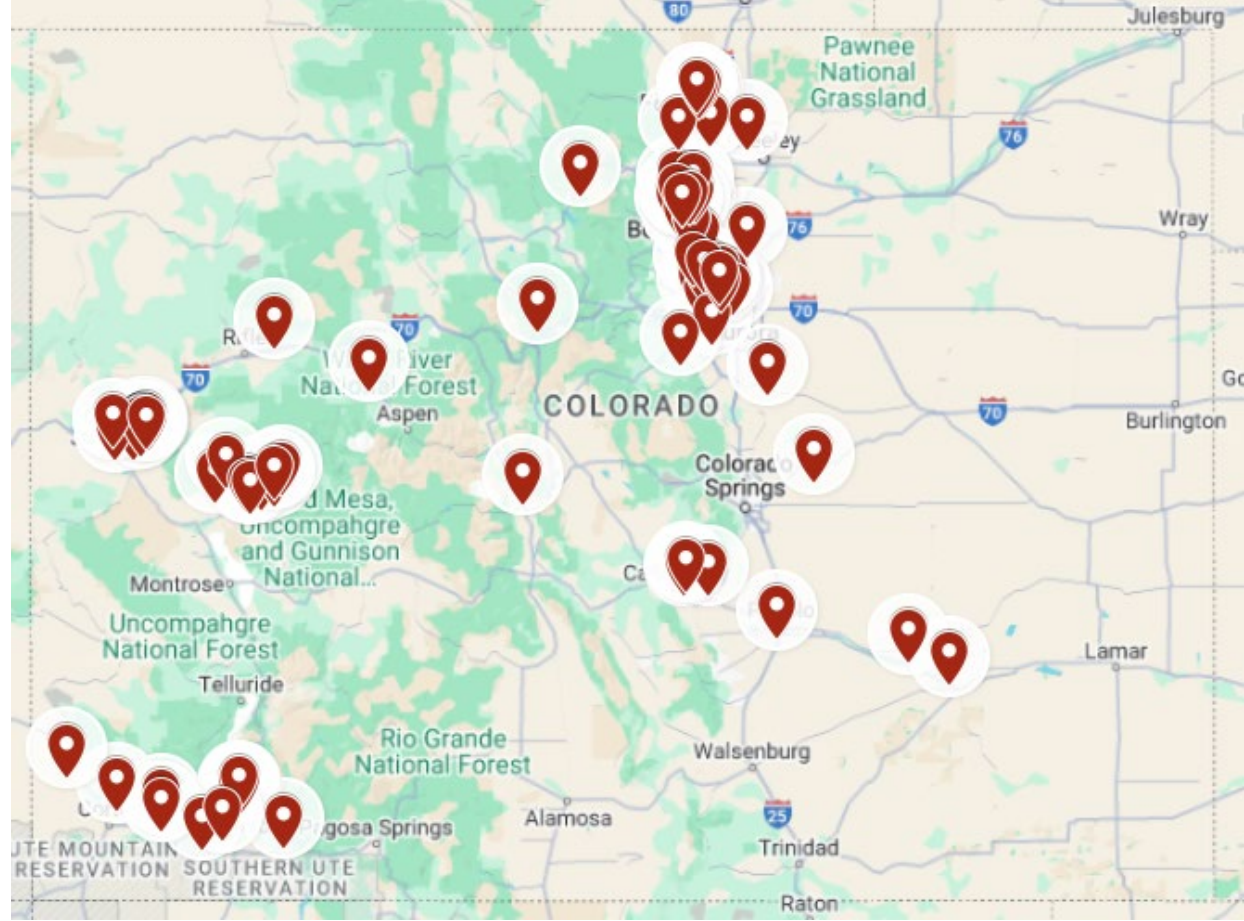
Sending a Message

Let the Farmer's Talk

We can't visit every farm so we will select farms in areas where it appears we have lower compliance or collusion to evade the program.

Our goal is to get the message circulating. The CDA will visit you, will confirm your status, and if you don't qualify for something you claim we will conduct an inspection at that time.

Qualified Exempt Farms



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Costs of Qualified Exempt

Qualified Exempt Status Verification:

More Qualified Exempt farms than Covered farms.

Covered farms registration rate is 81% compared to just 41% for Qualified Exempt farms.

Considerable additional time spent communicating to get needed information and confirm status for QE.

Attempt at Cost Control: Developed an Affidavit for the farms to attest they had reviewed their records as required annually and they met the requirements for Qualified Exempt status.

Killing Me Softly

Non-Recoverable Expenses:

Communication costs are higher for QE farms than covered farms.

Some pockets of QE are a days drive from Denver so increased travel costs will be required.

We enlisted other programs to assist with messaging across the state: CO Agricultural Workers Program for example.

All QE costs are outside the covered farm numbers associated with CAP funding levels.

Remain Committed

Recognize The Challenges:

While program budgets were cut the commitment to consumer safety and our farmer's financial viability from an outbreak or still paramount.

While we can't do more with less, making sure we close the loopholes that Qualified Exempt poses to the extent possible remains critical.

Communication and clarity are critical for everyone to succeed.

**Thank You.
Questions?**



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