

# Cyclospora Changes the Water-Safety Question

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*Why the 2026 Iceberg-Lettuce Outbreak Shows That Fresh-Produce Control Must Move Beyond Generic Indicator Microbiology*

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## Abstract

The 2026 U.S. Cyclospora outbreak linked to iceberg lettuce is a major food-safety signal. By the final CDC update, 12,883 laboratory-confirmed illnesses, 570 hospitalisations and two deaths had been associated with the outbreak. On 2 October, FDA closed its investigation after finding Cyclospora in two environmental samples in Mexico: outgoing wastewater at the processing facility and a drainage ditch at a traced grower. FDA explicitly stated that these findings do not establish the contamination route. That restraint is scientifically important. The event nevertheless exposes a structural weakness in fresh-produce water control: conventional indicator organisms and periodic water testing cannot by themselves characterise a human-specific protozoan hazard with complex environmental persistence, difficult detection and no simple culture-based infectivity assay. This article argues for a transition from “water compliance” to water-system hazard intelligence, integrating sanitary mapping, wastewater-source control, event-triggered surveillance, molecular detection, genotyping, process validation and supply-chain verification. The opportunity is not another disinfectant claim; it is a defensible, organism-aware architecture for agricultural and process-water safety.

**Keywords:** Cyclospora cayetanensis; agricultural water; fresh produce; food safety; FSMA; environmental surveillance; molecular detection; water-system risk

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**Meta Description:** The 2026 Cyclospora lettuce outbreak shows why fresh-produce safety needs water-system hazard intelligence, not indicator testing alone.

**Internal Tags:** Cyclospora; Agricultural Water; Fresh Produce; FSMA; Environmental Monitoring; Molecular Diagnostics; Food Safety; Water Treatment

## 1. The Signal: A Very Large Outbreak, and Two Environmental Positives

On 2 October 2026, the U.S. Food and Drug Administration (FDA) closed its investigation of the multistate *Cyclospora cayetanensis* outbreak linked to iceberg lettuce sourced from central Mexico. The final public-health burden was substantial: 12,883 laboratory-confirmed illnesses across 21 U.S. states, 570 hospitalisations and two deaths. The recalled product had been distributed broadly through foodservice and retail channels.

The most important new information is environmental. FDA's traceback converged on several farms and a processing facility in Mexico. During coordinated onsite inspections, FDA sampled water, soil, sediment and lettuce. Two environmental samples tested positive for *Cyclospora*: one from a tank holding outgoing wastewater at the processing facility and another from a drainage ditch at an iceberg-lettuce grower.

This is a strong epidemiological and environmental signal, but FDA made an essential qualification: the available evidence is still insufficient to determine conclusively how contamination occurred. Genotyping of the two positive environmental samples has been completed, while analysis continues on their relationship to clinical specimens.

That distinction should frame every technical interpretation of the event. Detection in the production environment is not equivalent to proof of the exact contamination pathway. The lesson is therefore not “a drainage ditch contaminated the lettuce” or “wastewater caused the outbreak”. Neither conclusion is currently established.

The defensible lesson is broader: a human faecal parasite was present within the environmental system in which implicated lettuce was grown and processed, and the outbreak reached a scale that demonstrates the limitations of treating agricultural-water safety as a narrow periodic-testing exercise.

## 2. *Cyclospora* Is Not a Conventional Bacterial Water Hazard

*Cyclospora cayetanensis* is a coccidian protozoan parasite. Humans are currently considered its only known host of public-health relevance. Oocysts are shed in faeces in a non-sporulated, non-infectious state and require time under suitable environmental conditions to sporulate and become infectious.

This biology has several practical consequences.

**First**, direct person-to-person transmission is considered unlikely because freshly excreted oocysts require environmental maturation. That makes environmental routes - especially water, sanitation failures, contaminated soil and produce-contact pathways - particularly important.

**Second**, the organism does not fit comfortably into the control logic developed for culturable enteric bacteria. Routine indicator organisms such as generic *E. coli* can be useful for characterising faecal contamination risk, but absence of an indicator at a sampling moment does not prove absence of *Cyclospora*.

**Third**, there is no simple routine culture method that gives the food industry an easy viable-count endpoint analogous to many bacterial systems. Molecular detection is therefore central, but detection of DNA and demonstration of infectivity are not the same proposition.

**Fourth**, fresh produce creates an unusually difficult risk context. Lettuce may be consumed raw, has a large and complex surface, can contact agricultural water repeatedly, and generally lacks a consumer kill step.

Cyclospora therefore exposes a methodological problem: food-safety systems designed around bacterial indicators and end-product sampling can miss hazards whose ecology, analytical detection and dose-response characteristics are fundamentally different.

### 3. What Is Established, Emerging and Still Unknown

A rigorous assessment should separate evidence levels.

**Established evidence.** Epidemiology and traceback linked the 2026 multistate outbreak to iceberg lettuce from Taylor Farms de Mexico. FDA detected Cyclospora in two environmental samples at sites included in the traceback investigation. CDC recorded 12,883 confirmed cases in the linked outbreak. Cyclospora can be transmitted through contaminated food and water, and fresh produce has repeatedly been implicated in previous outbreaks.

**Emerging evidence.** Molecular tools for Cyclospora detection and source tracking are improving. FDA's updated BAM Chapter 19b method has been validated using outbreak-linked produce. A 2026 LAMP assay provides another potentially useful detection platform. FDA and CDC are also expanding targeted amplicon sequencing and building a genotype database to improve source attribution.

**Expert interpretation.** The outbreak strengthens the case for treating water safety as a dynamic system property rather than a single microbiological specification. Water source, conveyance, adjacent land use, sanitation infrastructure, drainage, weather, worker hygiene and process-water management should be evaluated as connected variables.

**Unknown.** The precise route by which the 2026 lettuce became contaminated has not been established publicly. The relative contribution of irrigation water, environmental splash, flooding, drainage, human sanitation, processing water or other pathways remains unresolved.

**Research hypothesis.** A risk architecture combining sanitary-system mapping, event-triggered molecular surveillance and genomic linkage could identify high-risk environmental transitions earlier than periodic indicator testing alone. This hypothesis is technically plausible but requires prospective validation.

### 4. The Regulatory Timing Is Remarkable

The outbreak occurred just as the United States was moving into a new regulatory model for pre-harvest agricultural water. FDA's 2024 final rule amended Subpart E of the FSMA Produce Safety Rule. For covered produce other than sprouts, it replaced the previous pre-harvest microbial quality criteria and routine testing framework with a systems-based agricultural water assessment.

The new approach requires covered farms to evaluate water sources and distribution systems, water-use practices, crop characteristics, environmental conditions, adjacent and nearby land uses, and other relevant factors that can introduce known or reasonably foreseeable hazards. The compliance dates are staggered. Large covered farms were due to comply by 7 April 2025; small farms by 6 April 2026; very small farms by 5 April 2027.

This means the 2026 Cyclospora season unfolded during the practical implementation of a regulatory philosophy that is highly relevant to the outbreak: hazard identification should not be reduced to a single numerical water test. FDA's response after the outbreak reinforces that direction. On 2 October 2026, the agency announced ten planned activities before the 2027 growing season, including increased surveillance, stakeholder outreach, prevention work, publication of an outbreak investigation report and an update of its Cyclospora Prevention, Response and Research Action Plan.

## 5. Why Indicator Testing Cannot Carry the Whole Burden

Indicator organisms remain useful. The problem is treating them as universal proxies.

Generic *E. coli* is widely used because it is measurable, relatively inexpensive to test and informative about faecal contamination. But indicator-hazard relationships are conditional. They depend on source, timing, environmental persistence, transport, analytical recovery and the ecology of the target pathogen or parasite. A negative *E. coli* result does not logically establish that *Cyclospora* is absent. Conversely, an elevated indicator count can identify a sanitation problem without proving the presence of *Cyclospora*.

This is not a criticism of indicator microbiology. It is a criticism of over-interpreting what an indicator can prove. The correct question is therefore not: “Did the water pass?” It is: “What evidence supports the conclusion that this water system, under current environmental and operational conditions, is adequately controlled for the hazards reasonably expected to affect this crop and process?”

That is a more demanding question because it requires context. It also aligns with the direction of FDA’s revised agricultural-water rule.

## 6. Water Is a System, Not a Sample

A water sample is a snapshot. A water system is a moving network.

Agricultural water can originate from wells, canals, reservoirs, rivers or municipal supplies. It can pass through open channels, tanks, pumps, pipes and storage structures. It can be affected by animals, human sanitation, sewage infrastructure, runoff, flooding, sediment disturbance, maintenance failures and nearby land uses.

Processing water adds further complexity through flumes, wash tanks, recirculation loops, spray systems and wastewater interfaces. A useful safety model therefore needs spatial and temporal information.

Spatially, the system should identify upstream contamination sources, cross-connections, drainage routes, wastewater points, worker sanitation infrastructure and areas where contaminated water could move toward crops or food-contact operations. Temporally, it should recognise that risk changes after rainfall, flooding, infrastructure failure, unusual human activity, maintenance, water-source switching or seasonal changes.

A quarterly or monthly sample cannot represent all of those states. This is why a system-based assessment can be scientifically superior to a fixed-frequency testing programme - provided the assessment is substantive rather than bureaucratic.

## 7. The Wastewater Signal Deserves Special Attention

FDA found *Cyclospora* in a tank holding outgoing wastewater from the implicated processing facility. This does not prove that wastewater contaminated finished lettuce. Outgoing wastewater is, by definition, expected to collect material leaving operations and may reflect contamination already present elsewhere.

Nevertheless, wastewater can be a powerful surveillance matrix.

Wastewater epidemiology became globally visible during the COVID-19 pandemic, but the principle is broader: aggregated waste streams can reveal biological signals circulating through a facility or community. For fresh-produce operations, wastewater surveillance could potentially provide an early-warning function for human-specific enteric hazards, especially where direct product contamination is sporadic and difficult to detect. The idea requires caution. A positive wastewater result may not locate the source, establish viability or demonstrate food exposure. But it can trigger investigation.

That makes wastewater valuable not necessarily as a compliance endpoint, but as a sentinel matrix.

## 8. Drainage Is an Underappreciated Food-Safety Interface

The second positive sample came from a drainage ditch at a traced grower.

Again, this does not establish the contamination route. But drainage deserves more attention in produce-safety engineering. Food-safety plans tend to focus on water that is intentionally applied to crops. Environmental water moves whether or not it is designated as “agricultural water”. Rainfall can mobilise faecal contamination. Ditches can collect runoff from fields, roads, settlements or sanitation infrastructure. Flooding can reverse normal flow patterns. Aerosols, splash and sediment movement can create indirect contact routes.

A farm can therefore have a compliant irrigation source and still be exposed to an uncontrolled hydrological pathway. The practical implication is that agricultural-water assessments should include drainage topology, not only irrigation infrastructure. In high-risk settings, mapping the direction of water movement after heavy rain may be as important as analysing the irrigation source on a dry day.

## 9. Molecular Detection Is Improving - but Interpretation Still Matters

The analytical position has improved substantially.

In 2026, Rogers and Almeria reported validation of the updated FDA BAM Chapter 19b method for detection of *Cyclospora cayetanensis* in outbreak-linked fresh produce. The method provides a more robust regulatory laboratory tool for produce matrices. A separate 2026 study developed a loop-mediated isothermal amplification (LAMP) assay for *Cyclospora* detection. LAMP can offer operational advantages because amplification can occur under isothermal conditions and may support faster or less instrument-intensive workflows than conventional PCR in some settings.

FDA has also advanced targeted amplicon sequencing for genotyping. Its 2026 Action Plan states that FDA and CDC have demonstrated improved genetic resolution for linking food and clinical samples and are building a genotype database that includes hundreds of diverse specimens. These developments are important because detection answers “is *Cyclospora* DNA present?”, while genotyping begins to address “is this environmental or food signal genetically related to the clinical outbreak?”

But molecular power does not remove the need for epidemiology.

A genetic match is strongest when integrated with time, place, product movement and exposure data. Conversely, failure to detect the organism in a finished-product sample does not invalidate strong epidemiological evidence when contamination is heterogeneous and the implicated lots are no longer available.

## 10. The False-Positive Episode Is a Useful Scientific Lesson

During the July investigation, FDA initially reported a positive lettuce sample collected at the border. Laboratory experts subsequently re-reviewed the result and concluded that it did not represent true amplification; the finding was reclassified as a false positive. This correction is not a weakness of the investigation. It is evidence of appropriate analytical governance.

High-sensitivity molecular methods operate near detection limits in complex matrices. Contamination can be sparse. Amplification curves can be ambiguous. Controls, repeat analysis and expert review matter. The episode illustrates why a serious *Cyclospora* monitoring programme needs predefined rules for:

- presumptive positives;
- confirmatory testing;
- inhibition controls;
- replicate analysis;

- contamination control;
- chain of custody;
- interpretation of low-level signals;
- communication before confirmation.

Rapid testing without disciplined interpretation can generate false reassurance or false alarm.

## 11. Washing Is Not a Kill Step

Consumers are commonly advised to wash fresh produce, and washing can reduce soil and some surface contamination. It should not be presented as a reliable *Cyclospora* elimination step. Fresh leafy vegetables have folds, damaged tissue and microsites that complicate removal. Oocysts can adhere to surfaces, and household washing lacks a validated lethality endpoint.

The industrial implication is more important: post-harvest washing should not be treated as a substitute for preventing faecal contamination upstream. Wash-water management remains essential because poorly controlled systems can redistribute contamination between product units. But the strongest control remains exclusion of the hazard from the water-crop-process environment in the first place.

This is a classic preventive-control hierarchy: prevention is more defensible than attempting to wash away an intermittently distributed protozoan hazard after contamination has occurred.

## 12. Treatment Technologies: Do Not Generalise from Bacteria

Water-treatment technologies can be valuable, but claims must be organism-specific.

Chlorine, chlorine dioxide, ozone, UV, filtration, advanced oxidation and other approaches have different performance depending on water chemistry, turbidity, organic load, contact time, dose, reactor design and target organism. A treatment that achieves a validated log reduction for *E. coli* or *Salmonella* cannot automatically be assumed to achieve the same reduction for *Cyclospora* oocysts.

This is particularly important for commercial technologies marketed for agricultural or process water.

The scientifically defensible hierarchy is:

1. define the target hazard;
2. define the water matrix;
3. establish a validated analytical or surrogate endpoint;
4. determine dose/contact conditions;
5. measure performance under worst-case operational conditions;
6. verify that the treatment does not create unacceptable residues or process effects;
7. implement continuous or frequent process verification where feasible.

For *Cyclospora*, validation is complicated by the limited availability of infectivity assays and the difficulty of routine viability measurement. This is exactly why overclaiming must be avoided.

## 13. EU and Spain: A Different Legal Architecture, the Same Biological Problem

The European Union does not replicate the U.S. FSMA agricultural-water framework.

Regulation (EC) No 853/2004 establishes general hygiene obligations across food production. At primary-production level, operators must take adequate measures to prevent contamination and, where necessary, use potable water or clean water to prevent contamination. Food businesses beyond primary production are subject to broader hygiene and HACCP-based obligations. For Spain, these EU requirements apply directly alongside national official-control and food-safety structures. The legal architecture is therefore less

prescriptive than the current U.S. systems-based pre-harvest agricultural-water assessment. But the biological hazard does not change at the border.

European growers and processors supplying ready-to-eat fresh produce should therefore interpret general hygiene obligations dynamically. Where *Cyclospora* is a reasonably foreseeable hazard - because of geography, imported supply, sanitation conditions, water source or outbreak history - generic compliance with water documentation may not be enough to demonstrate effective control. This is an area in which U.S. regulatory learning can be technically useful to EU operators even when it is not legally binding in Europe.

## 14. Importers Are Part of the Water-Safety System

The 2026 outbreak also demonstrates that agricultural-water control cannot stop at the farm gate.

FDA's Foreign Supplier Verification Program requires U.S. importers to verify that foreign suppliers produce food in compliance with applicable U.S. safety standards. FDA's 2026 *Cyclospora* Action Plan explicitly identifies FSVP as a prevention tool and states that importers must verify that foreign suppliers apply standards that mitigate *Cyclospora* contamination comparably to domestic requirements.

For ingredient and food companies, this changes supplier qualification.

A supplier questionnaire asking "Is your water tested?" is inadequate.

More meaningful questions include:

- What water sources are used at each production stage?
- What adjacent land and sanitation hazards exist?
- How is drainage managed?
- What events trigger reassessment or testing?
- Are process-water systems recirculated?
- How are wastewater and clean-water flows segregated?
- Which analytical methods are used?
- What happens after an environmental positive?
- Can water-system changes be traced to affected lots?

Supplier verification should test the logic of the control system, not merely collect certificates.

## 15. Research & Innovation Opportunity

### Water-System Hazard Intelligence for Fresh Produce

**Unresolved problem.** Agricultural and process-water safety is still often managed through fragmented data: periodic microbiology, paper maps, maintenance records, weather data, sanitation observations and supplier documents. These datasets rarely operate as one risk system.

**Why it matters.** *Cyclospora* contamination is intermittent, environmentally mediated and analytically difficult. Static sampling can miss short-lived but consequential contamination events.

**What is already known.** FDA's revised Produce Safety Rule already embraces systems-based water assessment. Molecular detection and genotyping methods are improving. Weather, hydrological and geospatial data are increasingly accessible. Environmental monitoring is well established in other areas of food manufacturing.

**What remains unknown.** There is no validated, widely adopted model that combines hydrology, sanitation, environmental events and organism-specific surveillance to predict when *Cyclospora* sampling or intervention is most valuable.

**Proposed hypothesis.** A dynamic hazard-intelligence platform could identify periods and locations of elevated *Cyclospora* risk more efficiently than fixed-frequency testing alone.

A prototype architecture could integrate: ***water source + drainage topology + sanitation infrastructure + rainfall/flooding + land use + worker sanitation + process-water flows + indicator microbiology + Cyclospora PCR + wastewater surveillance + genotyping + lot traceability.***

#### **Validation steps.**

1. Map water and drainage networks at participating farms and processors.
2. Establish baseline indicator and *Cyclospora* surveillance.
3. Record rainfall, flooding, infrastructure failures and sanitation events.
4. Define event-trigger thresholds for intensified sampling.
5. Compare fixed-frequency versus risk-triggered detection yield.
6. Link environmental results to product lots and downstream distribution.
7. Evaluate false-positive, false-negative and operational response rates.
8. Validate the model prospectively across multiple growing seasons and regions.

**Regulatory constraints.** The platform would support, not replace, statutory agricultural-water and hygiene requirements. Analytical methods used for regulatory decisions would still need appropriate validation and competent-authority acceptance.

**Industrial relevance.** A successful system could improve prevention, target sampling expenditure, strengthen supplier verification and shorten outbreak source attribution.

This is a proposed research programme, not an established regulatory method.

## **16. A Second Research Opportunity: Viability, Not Just DNA**

*Cyclospora* control remains constrained by a fundamental analytical gap: PCR can detect DNA, but DNA detection does not necessarily establish that oocysts are viable and infectious.

This limits treatment validation.

An important research priority is therefore a practical viability or infectivity proxy suitable for water and produce studies. Potential avenues include molecular markers associated with sporulation, integrity-based PCR approaches, metabolic assays, advanced imaging, transcriptomic signals or validated surrogate organisms.

Each approach has limitations. Surrogates can differ from *Cyclospora* in resistance. Membrane-integrity assays do not always predict infectivity. RNA can persist after loss of infectivity. Direct human infectivity studies are obviously inappropriate.

The objective should not be to force a convenient assay into a claim.

It should be to build a weight-of-evidence validation framework in which physical integrity, molecular activity, sporulation status and surrogate performance are combined transparently.

Without better viability tools, the industry will continue to face a gap between “we reduced the molecular signal” and “we reduced the infectious hazard”.

## **17. Implications for Process-Water Technologies**

For companies developing process-water technologies, the 2026 outbreak is strategically relevant but must not be used opportunistically.

A technology intended to condition, treat or control water should not claim efficacy against *Cyclospora* unless that efficacy has been specifically demonstrated under relevant conditions.

This is particularly important for INTABIOTECH's water-technology domain. The scientifically credible opportunity is not to infer that an existing antibacterial effect extends automatically to protozoan oocysts.

The correct R&D pathway would be:

- characterise the technology's physicochemical action in the target water;
- determine whether a plausible mechanism exists against oocyst integrity or sporulation;
- select an appropriate validated *Cyclospora* method and, if necessary, justified surrogates;
- conduct controlled concentration/contact-time experiments;
- test high-organic-load and turbid conditions;
- assess persistence or recovery after treatment;
- verify compatibility with food-contact and process requirements;
- only then define the permissible technical claim.

A negative result would still be scientifically valuable because it would prevent an unsupported application claim. A positive result, if independently reproducible, could open a meaningful new research line.

## 18. From HACCP to Hydrological HACCP

HACCP traditionally organises food safety around process steps.

Fresh-produce water risk often originates outside the linear process flow.

Rain falls upstream. Drainage crosses property boundaries. Human sanitation systems fail. Surface water moves between locations. Irrigation and wastewater networks can intersect indirectly.

This suggests a useful conceptual extension: **hydrological HACCP**.

The term is proposed here as an analytical framework, not as a new legal HACCP category.

Its purpose would be to map hazard movement through water rather than only through product flow.

A hydrological HACCP study would identify:

- water entry points;
- upstream contamination sources;
- flow directions;
- storage points;
- cross-connections;
- drainage;
- flood pathways;
- wastewater interfaces;
- crop-contact points;
- process-water loops;
- intervention points;
- verification points.

The resulting map could sit alongside the conventional process-flow diagram.

For water-sensitive fresh produce, that second map may reveal hazards that the process diagram cannot.

## 19. Practical Actions for Industry Now

The 2026 outbreak does not justify panic, nor does it justify waiting for the next outbreak report.

Fresh-produce growers, processors and importers can act now.

**First**, review agricultural and process-water hazard assessments specifically for human faecal contamination routes.

**Second**, map drainage and wastewater as carefully as irrigation.

**Third**, establish event-triggered reassessment after heavy rainfall, flooding, sewage incidents, infrastructure failure or water-source changes.

**Fourth**, confirm that laboratories use appropriate validated methods for *Cyclospora* when organism-specific testing is warranted.

**Fifth**, define how presumptive and confirmed molecular positives will be handled before a positive occurs.

**Sixth**, verify foreign suppliers through system evidence rather than certificates alone.

**Seventh**, assess whether wash-water controls prevent cross-contamination without pretending that washing is a validated *Cyclospora* kill step.

**Eighth**, connect environmental monitoring to lot traceability.

**Ninth**, retain sufficient metadata - location, date, water source, weather, crop block and process conditions - to make a future molecular result interpretable.

**Tenth**, distinguish clearly between control of general microbial water quality and demonstrated control of *Cyclospora*.

## 20. Conclusions

The 2026 iceberg-lettuce outbreak is one of the clearest recent demonstrations that fresh-produce safety is inseparable from environmental water systems. The outbreak affected 12,883 confirmed patients and led FDA investigators to identify *Cyclospora* in wastewater and drainage environments associated with traced operations. Those findings do not establish the contamination route, and they should not be overstated. They do, however, show why a pass/fail concept of “water quality” is too narrow.

*Cyclospora* is a human-specific protozoan hazard with unusual environmental biology, difficult detection and no convenient routine infectivity assay. Its control requires more than periodic indicator microbiology. The regulatory direction in the United States is already moving toward systems-based agricultural-water assessment. The scientific direction should go further: hydrological mapping, event-triggered surveillance, organism-specific molecular methods, genotyping, wastewater sentinels, supplier-system verification and better viability tools.

For Europe and Spain, the legal structure differs, but the biological problem is identical. The central proposition is therefore simple: ***Water safety is not a laboratory result. It is a continuously changing property of a biological, hydrological and operational system.***

The companies that understand that distinction will be better prepared not only for *Cyclospora*, but for the next environmental hazard that conventional specifications fail to see.

## Related Knowledge Areas

- *Food Safety* — protozoan hazards, environmental monitoring and preventive controls.
- *Processing Technologies* — process-water management, sanitation and treatment validation.
- *Regulatory Affairs* — FSMA agricultural-water requirements, EU hygiene law and supplier verification.
- *AI & Food* — event-triggered surveillance, hydrological risk modelling and data integration.

- *Mineral Technologies* — organism-specific validation of water-conditioning technologies.
- *Emerging Research* — Cyclospora viability, genotyping, wastewater surveillance and hydrological HACCP.

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